

# 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:** Aug 31, 2018  
**To:** "Emma Longley Barber" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-18-1468

RE: Manuscript Number ONG-18-1468

Race and Route of Hysterectomy: Examining Disparities in Postoperative Complications

Dear Dr. Barber:

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 Sep 21, 2018, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1: Overall: This is a well written paper on a timely topic. The authors used the NSQIP Database to investigate association between race and route of hysterectomy, and also race and postoperative complications. Their findings, that black women undergo more open hysterectomy even when accounting for contributing factors to an open case, is important.

There are some places where the manuscript could be written more clearly to ensure generalist obgyns in practice, who do not use statistics everyday, will enjoy reading the paper.

Overall please be careful with the use of the words risk ratio and rate. A rate is reserved for a numerator over a denominator that includes time.

The authors report no conflict of interest

IRB application was submitted and the authors report that the study was deemed exempt.

The title and Precis are fine.

1. Line 60-61: This sentence needs a citation. Is "most evidence" a number of papers? To provide context, or the gap that the authors sought to fill with their study a specific comment or statement about the number of existing papers would be helpful here.

2. Line 63: Can the authors use a number instead of the word "higher".

3. Line 129: This is an important paragraph. Please include a strong topic sentence. Here the use of rate requires a time denominator - per year? woman-year?

4. Lines 137-142: Needs some editing because the importance of the information is lost in the long sentence. Please correct risk and odds and choose one - which presumably is odds because that's what is reported at the end of the sentence.

5. Overall the Discussion is well organized but the lack of specifics makes it hard to follow at times. Be specific and use author names for studies. At times it's hard to distinguish the manuscript from previously published literature.

6. Lines 144-150: The authors correctly identify that their findings are similar to other studies - then why should this

paper be published? What sets this paper apart from others?

7. Lines 159-160 - this is a good point? Should this be a focus of your discussion and if so shouldn't it be moved to the first paragraph of the discussion?

8. Lines 157-158: What other contributing factors warrant further investigation?

tables and figures:

9. Table 1: Please remove the decimals in the percentages, they make the table harder to read. Also the table needs a longer title - tables need to stand alone without needing to read the text. The overall column isn't needed.

10. Both tables 3 and 4 are not needed. Table 4 should be titled specifically "the odds of having a complication given black race, stratified by route of surgery"

Reviewer #2: This paper largely confirms findings of prior studies regarding the relative likelihood of surgical route and the relative risk of postoperative complications of black and white women. It is generally well presented and discussed. I have several comments for the authors to consider.

#### Title

1. The title implies that the primary outcome of interest was complications, not route of hysterectomy, which is the primary outcome. In addition, all races were not considered. A more accurate title should be provided.

#### Abstract

2. The abstract was likely written for the SGO meeting, before the final text and calculations were created, and not amended since. Thus, nearly every number in the abstract does not correspond with those in the text and tables. The most striking disparity is for uterine weights (the abstract says median weights while Table 1 does not specify, but I assume these are means to explain the magnitude of the difference). However, most of the numbers in lines 43-45 differ from those in the text and tables. In addition, the odds ratios for unadjusted risks of major and minor complications by race noted in the abstract are not presented in the results or Table 3.

#### Methods.

3. The authors combine laparoscopic, robotic, laparoscopically assisted vaginal hysterectomy and vaginal hysterectomies as minimally invasive. However, when examining bivariate risks of complications, they analyzed vaginal and laparoscopic routes separately. Were robotic and laparoscopically assisted vaginal hysterectomies included (if so, how?) or excluded from this analysis?

4. Were Asian, Hispanic and Native American women excluded from analysis?

5. Lines 99 and 109. The confounders are listed parenthetically in the results section, but since they were selected a priori, they should be specified in the methods section instead. In addition, the specific "comorbidities" used in the complications regression model should be specified.

6. The decision to model uterine weight as a binary variable is not well defended.

#### Results

7. Line 121. The end of the line should read "... prior abdominal surgery" rather than "... prior pelvic surgery."

8. Since some of the subgroups in the MIS surgical group are included in the analysis of complications, it would be good to include the number of women undergoing each of the four MIS procedures in Table 1.

9. Lines 132-3. Was the lack of significant difference in major, minor or overall complications rates in the vaginal hysterectomy subgroup considered valid or was it related to the small sample size? I think this finding, if real, has important implications and should be included in the discussion.

#### Discussion

10. The authors do a good job of putting the study into context and discussing strengths and limitations of the study. However, I would include an inability to assess the skill and surgical volume of the operator is an important confounder that is neither measured nor discussed. Might a low volume operator who is uncomfortable performing vaginal hysterectomies and/or laparoscopic procedures be also more prone open surgery and to complications?

Reviewer #3: The authors examined data from 15,000 patients in the NSQIP database undergoing hysterectomy and

compared the use of minimally invasive surgery (MIS) and postoperative minor and major complications among white and black patients. This analysis differs from others because it controls for appropriate clinical factors (e.g. uterine size, obesity, etc) which could well be confounders for these outcomes. Black women were significantly more likely to undergo an open hysterectomy than white women (50% vs 20%), even when accounting for factors such as fibroid burden and number of prior surgeries. Black women were also more likely to experience minor and major complications, even when accounting for co-morbidities and route of hysterectomy. The authors, I believe correctly, interpret this as a likely disparity in access to quality care as other data demonstrate that within the same hospital systems, black women are equally likely to undergo minimally invasive hysterectomy.

The paper is quite well-written, concise, and understandable. The methods are sound and the limitations are few. The subject is relevant to a wide audience and had important clinical and public health implications. Kudos on a job well done.

A minor point:

In general, I've never been very supportive of using a cut-off of 250g to definite greater complexity in hysterectomy. Clinical experience with the laparoscopic approach indicates that significant differences in the challenge of the operation occur at much larger sizes. That said, the authors modeled the analysis both continuously and categorically with no difference in their conclusions. Using 250g as a cut-off I imagine made the analysis simpler to understand without changing interpretation of the data overall.

#### STATISTICAL EDITOR'S COMMENTS:

1. Table 1: parity can only have integer values. Should cite as median(IQR or range) and test non-parametrically. uterine wgt is often skewed. If non-normal distribution, should cite as median (IQR or range) and test non-parametrically.
2. Tables 3 and 4: This is a large study, but the counts of adverse outcomes for major complications are relatively small in some subsets. It would be useful to complement the adjusted model analysis with matching (eg, propensity score matching), since there are so many significantly different baseline variables which potentially could affect outcomes.

#### ASSOCIATE EDITOR-GYN'S COMMENTS:

- 1 - Please complement the adjusted model analysis with propensity score matching as suggested by the STAT Editor
- 2 - Rev #3 raises a common point which is the somewhat arbitrary cut-off of 250 gm when the clinician's presumption is that black women have much larger uteri than whites. For example, if blacks had huge uteri and whites were mainly 250-350 gm then this would not be analyze-able within their dataset and the whole argument would be inaccurate as the reason blacks need TAH more often is simple: they have much bigger uteri. One way of putting this to rest would be to compare the <250 gm pts: if there is a disparity there, then it would serve as a reasonable proxy that there really is a disparity. The Discussion should speak to this point as well.

#### 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. 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.
3. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology 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>.
4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 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.

5. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement form verifies that permission has been obtained from all named persons.
- \* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

6. 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, written in the present tense and stating 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."

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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

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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, 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 Sep 21, 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

If you would like your personal information to be removed from the database, please contact the publication office.





The Editorial Board

*Obstetrics and Gynecology*

September 16<sup>th</sup>, 2018

To the Editors,

I am writing to submit revisions to the manuscript entitled “Black Race and Hysterectomy: Examining Disparities in Route of Surgery and Postoperative Complications”.

We appreciate the opportunity to revise and resubmit our work and believe it has been strengthened by the changes prompted by the suggestions of the reviewers. Attached in this document are a detailed list of each suggested change and our response.

We appreciate the opportunity to submit our work and thank the reviewers and editors for their time and consideration.

Sincerely,

A handwritten signature in black ink that reads "Emma Barber".

Emma L Barber



**Reviewer 1, Comment #1:** 1. Line 60-61: This sentence needs a citation. Is "most evidence" a number of papers? To provide context, or the gap that the authors sought to fill with their study a specific comment or statement about the number of existing papers would be helpful here.

**Response:** The sentence now reflects that there are several recent papers and provide the references to these papers.

**Change:** Line 78-79 "Several recent papers written in regards to disparities in route of hysterectomy utilize secondary datasets that do not account for differences in patient populations.<sup>6-8</sup>"

**Reviewer 1, Comment #2:** Line 63: Can the authors use a number instead of the word "higher".

**Response:** Thank you for this suggestion, a more descriptive phrase has been added.

**Change:** Line 80: "In particular, Black women are two to three times more likely to experience uterine fibroids and, as a result, may have larger uteri, which could contribute to higher rates of open hysterectomies"

**Reviewer 1, Comment #3:** Line 129: This is an important paragraph. Please include a strong topic sentence. Here the use of rate requires a time denominator - per year? woman-year?

**Response:** Thank you for this correction. A better description instead of rate is proportion. This has been changed in all key portions of the manuscript.

**Change:** Line 159-163: "A larger proportion of black women experienced complications when undergoing hysterectomy compared to white women, though stratified analysis showed that the proportion varied by type of hysterectomy (Table 3). When considering all methods of hysterectomy black women experienced more total complications (14.1% vs. 8.6%,  $p < 0.001$ ), more major complications (4.1 vs. 2.4%,  $p < 0.001$ ) and more minor complications (11.4% vs. 6.7%,  $p < 0.001$ )."





**Reviewer 1 Comment #4.** Lines 137-142: Needs some editing because the importance of the information is lost in the long sentence. Please correct risk and odds and choose one - which presumably is odds because that's what is reported at the end of the sentence.

**Response:** Odds is a better word choice given a logistic regression was performed. The paragraph has been edited substantially for clarity.

**Change:** Lines 159-182 “A larger proportion of black women experienced complications when undergoing hysterectomy compared to white women, though stratified analysis showed that the proportion varied by type of hysterectomy (table 3). When considering all methods of hysterectomy black women experienced more total complications (14.1% vs. 8.6%,  $p<0.001$ ), more major complications (4.1 vs. 2.4%,  $p<0.001$ ) and more minor complications (11.4% vs. 6.7%,  $p<0.001$ ). When examining patients who underwent vaginal hysterectomy there were no differences in the proportion of women who had complications for black versus white women, though there was a small sample size. When examining only open hysterectomy, black women had greater number of minor complications (16.9% vs 11.3%,  $p<0.001$ ). Lastly, when women underwent laparoscopic hysterectomy, black women had more major complications when compared to white women (3.3% vs 1.8%,  $p<0.001$ ). “

To adjust for factors that might place a patient at higher odds of developing a complication, a logistic regression was performed (table 4). The regression showed that after adjustment for clinical factors black women still had higher odds of postoperative complications, though the odds were decreased (major aOR: 1.56, CI: 1.25-1.95, minor aOR: 1.27, CI: 1.11-1.47).

**Reviewer #1, Comment 5.** Overall the Discussion is well organized but the lack of specifics makes it hard to follow at times. Be specific and use author names for studies. At times it's hard to distinguish the manuscript from previously published literature.

**Response:** Author's names have been added to specifically referenced studies and small changes made through out to better clarify.

**Reviewer #1, Comment 6** L Lines 144-150: The authors correctly identify that their findings are similar to other studies - then why should this paper be published? What sets this paper apart foremothers?

**Response:** Previous papers have not been able to account for individual factors that may be different between black and white women in a large dataset. These factors, such as uterine size, previous medical and surgical history and the other factors accounted for in this analysis are the primary drivers of preoperative surgical decision making regarding route of surgery. Additionally, this analysis shows that black women receive less minimally invasive surgery and this may be a driving force behind increased surgical complications experienced by black women. This may lead to a possible intervention to increase quality of care for black women receiving hysterectomy.

We first introduced this concept by referring to these papers in lines 80-82: "Several recent papers written in regards to disparities in route of hysterectomy utilize secondary datasets that do not account for differences in patient populations."<sup>6-8</sup> We also highlighted what our paper contributes in the discussion section, lines 239-254: "One possible explanation for our findings is that women of minority race might have disparate access to gynecologic care. The previous literature incompletely answers this issue. Ranjit et al., attempted to answer this question by examining women of equivalent insurance and, therefore, presumably equal access to care. They found that black women



still had greater odds of undergoing an open hysterectomy, however did not fully take into consideration patient level factors.<sup>7</sup> In another study, by Price et al, a small sample size of patients from three hospitals with high rates of minimally invasive hysterectomy found that black women did not have an increased odds of having an open hysterectomy, when controlling for other factors, including uterine size. <sup>6</sup> The findings of Price et al, suggests that access to care and quality of hospital care may be important factors to investigate.”

**Reviewer #1, Comment 7:** Lines 159-160 - this is a good point? Should this be a focus of your discussion and if so shouldn't it be moved to the first paragraph of the discussion?

**Response:** Thank you for this comment, we agree that this is an important point, and have therefore included it in the discussion. However given that our paper is suggestive of this hypothesis but cannot directly confirm this hypothesis we chose to place it later in the discussion.

**Reviewer #1, Comment 8.** Lines 157-158: What other contributing factors warrant further investigation?

**Response:** The factors referred to in this sentence lead into the next paragraph regarding disparate access to gynecologic care, likely the most important factors that may contribute to differing rates of complications. Other factors mentioned in disparity literature include inherent bias of providers, geographic location of patients to the hospitals at which they receive treatment and lack of health education. However, given these are complicated concepts, we have chosen to omit them given it seemed difficult to bring up in a short, succinct and well supported manner.

**Reviewer 1, Comment 9.** Table 1: Please remove the decimals in the percentages, they make the table harder to read. Also the table needs a longer title - tables need to stand alone without needing to read the text. The overall column isn't needed.



**Response:** Thank you for this feedback regarding the tables to make them more reader friendly. The title of table one has been changed. Some of the decimal places were longer than one place, likely making the table much harder to read, this has been remedied. However, given some of the large groups, some of the percentages would not add up to 100%, even with careful rounding, as such we have elected to leave one decimal place in for clarity.

We understand that the addition of an overall column may not be necessary, however, it does allow the reader to easily compare each group (white and black women) to the overall percentage. As such, we have elected to retain this column, but could remove it if the editor feels it necessary.

**Reviewer 1, Comment 10.** Both tables 3 and 4 are not needed. Table 4 should be titled specifically "the odds of having a complication given black race, stratified by route of surgery"

**Response:** The title of table 4 has been changed to more accurately describe the table. We do not specifically address all the odds ratios or proportions discussed in these tables, therefore feel both tables add value to the manuscript. Further, table 3 gives the number of complications included in our multivariable regression analysis which gives the reader insight into the robustness of our models.

**Reviewer 2 Comments:**

**Reviewer 2, Comment 1:** The title implies that the primary outcome of interest was complications, not route of hysterectomy, which is the primary outcome. In addition, all races were not considered. A more accurate title should be provided.

**Response:** We have changed the title to more accurately reflect the contents of the manuscript.

**Change:** "Black Race and Hysterectomy: Examining Disparities in Route of Surgery and Postoperative Complications"



**Reviewer 2, Comment 2.** The abstract was likely written for the SGO meeting, before the final text and calculations were created, and not amended since. Thus, nearly every number in the abstract does not correspond with those in the text and tables. The most striking disparity is for uterine weights (the abstract says median weights while Table 1 does not specify, but I assume these are means to explain the magnitude of the difference). However, most of the numbers in lines 43-45 differ from those in the text and tables. In addition, the odds ratios for unadjusted risks of major and minor complications by race noted in the abstract are not presented in the results or Table 3.

**Response:** Thank you for this important insight. The numbers have been corrected to reflect the final, refined analysis.

**Reviewer 2, Comment 3.** The authors combine laparoscopic, robotic, laparoscopically assisted vaginal hysterectomy and vaginal hysterectomies as minimally invasive. However, when examining bivariate risks of complications, they analyzed vaginal and laparoscopic routes separately. Were robotic and laparoscopically assisted vaginal hysterectomies included (if so, how?) or excluded from this analysis?

**Response:** Robotic and laparoscopically assisted hysterectomies were categorized as laparoscopic.

Given that the predominant part of the surgery of a laparoscopic assisted vaginal hysterectomy is often performed laparoscopically we have opted to include this in the laparoscopic group.

Additionally, robotic surgery and laparoscopic surgery share a common CPT code so these cannot be separated from each other in this data source. Given that minimally invasive surgery, whether laparoscopic, robotic, vaginal or laparoscopic assisted vaginal hysterectomy are all classified as



“minimally invasive”, we have opted to group them together for this analysis as vaginal hysterectomy alone is a fairly small sample size with small number of events.

**Reviewer 2, Comment 4.** Were Asian, Hispanic and Native American women excluded from analysis?

**Response:** Thank you for closely looking at the cohort included. These women were excluded from the analysis. The number of Asian and native American women in the database were fairly small. Additionally Hispanic is listed as an ethnicity, not a race and there are both black and white women that may have Hispanic ethnicity. Given this complicating factor we opted to use the race variable alone and not focus on ethnicity.

**Reviewer 2, Comment 5.** Lines 99 and 109. The confounders are listed parenthetically in the results section, but since they were selected a priori, they should be specified in the methods section instead. In addition, the specific "comorbidities" used in the complications regression model should be specified.

**Response:** The confounders have been moved to the methods section as opposed to the results section. See new lines 127-128 & 140-142.

Changes: Lines 127-18 “Confounders were defined a priori and were selected by considering clinical factors that may be taken into consideration when selecting route of hysterectomy including uterine weight, prior abdominal or pelvic surgery, endometriosis, BMI, age, and comorbidities.<sup>17-19</sup>” Lines 140-142: “For this model, confounders were again defined a priori by selecting clinical factors that are known to be associated with postoperative complications. The factors accounted for included: prior abdominal surgery, prior pelvic surgery, endometriosis, BMI, age, comorbidities, procedures performed at the time of hysterectomy and route of hysterectomy (open versus minimally invasive).



**Reviewer 2, Comment 6.** The decision to model uterine weight as a binary variable is not well defended.

**Response:** This point was made by another reviewer as well as by the author. This was, perhaps, the most difficult decision of the analysis as uterine weight is considerably different between black and white women and also is one of the most important drivers of surgical decision-making. However, we felt it very important to consider that uterine weight is not available as a preoperative consideration, and thus chose to model this variable as binary--- small or large uterus. We feel this decision is further supported by the fact that our results were unchanged when modeling uterine weight as a continuous variable. Given the importance of this modeling choice, we have added information regarding modeling uterine weight as a categorical (small, medium and large) as well as using a different cut off point as a binary variable to add to our argument of modeling uterine weight as a binary variable.

**Change:** lines 125- 130: “We tested uterine weight as a continuous, categorical (<250g, 250-499g, 500-100g and >1000g) and binary (<250g, ≥250g) variable. Modeling uterine weight in different ways resulted in little variation to the adjusted odds ratio and overall model fit. Ultimately, we chose to model uterine weight as a binary variable, either smaller or greater than 250 grams, as most clinicians are able to approximate uterine size as large or small, based on clinical exam prior to surgery and because 250 grams has been used as a benchmark for higher reimbursement, due to greater surgical complexity.<sup>20</sup>”

Lines 138-144: “Sensitivity analyses were performed to ensure our models were robust. First, given the large difference in median uterine weight of black versus white women, we limited our analysis to women with uterine weight less than 250g for both races to examine the possibility that uterine weight drives our adjusted analysis. “



Lines 164-166: "When the analysis was limited to only women with small uterine size (weight <250g), black women remained at significantly higher odds of undergoing open hysterectomy (aOR 1.84, 95%CI 1.61-2.11, supplemental table 1)."

**Reviewer 2, Comment 7.** Line 121. The end of the line should read "... prior abdominal surgery" rather than "... prior pelvic surgery."

**Response:** Thank you for catching this oversight.

**Change:** Lines 157-158 "Black patients were younger, had a higher BMI, were more likely to have diabetes and hypertension, had a higher median uterine weight, and a higher incidence of prior abdominal surgery. However, white patients were more likely to have a diagnosis of endometriosis and have a history of prior pelvic surgery."

**Reviewer 2, Comment 8.** Since some of the subgroups in the MIS surgical group are included in the analysis of complications, it would be good to include the number of women undergoing each of the four MIS procedures in Table 1.

**Response:** Thank you for this suggestion, given that we described these MIS surgical procedures separately we have included them in table 1.

**Reviewer 2, Comment 9.** Lines 132-3. Was the lack of significant difference in major, minor or overall complications rates in the vaginal hysterectomy subgroup considered valid or was it related to the small sample size? I think this finding, if real, has important implications and should be included in the discussion.

**Response:** Thank you for this thought. Given that the vaginal hysterectomy numbers are much lower than both open and laparoscopic, it is likely that the lack of difference is due to the very small size and number of complications. Given the small number of complications, it was not possible to perform a logistic regression on this group separately with a sound model, thus we chose to include





this group in the minimally invasive group. Again, given the lack of difference between groups may be due to the very small numbers, we opted not to focus on this in our discussion.

**Reviewer 2, Comment 10.** The authors do a good job of putting the study into context and discussing strengths and limitations of the study. However, I would include an inability to assess the skill and surgical volume of the operator is an important confounder that is neither measured nor discussed. Might a low volume operator who is uncomfortable performing vaginal hysterectomies and/or laparoscopic procedures be also more prone open surgery and to complications?

**Response:** Thank you for adding another suggestion of unmeasured bias. Surgeon skill, volume and experience is likely a very important factor and would be an excellent subject of further research. We have reflected these thoughts in our conclusion:

**Change:** Lines 273-275: “Lastly, the database gives no information regarding surgeon volume or years of experience which may be important contributors to complication rates and may additionally provide insight into the physicians that are caring for black women.”

**Reviewer 3, Comment 1:**

In general, I've never been very supportive of using a cut-off of 250g to definite greater complexity in hysterectomy. Clinical experience with the laparoscopic approach indicates that significant differences in the challenge of the operation occur at much larger sizes. That said, the authors modeled the analysis both continuously and categorically with no difference in their conclusions. Using 250g as a cut-off I imagine made the analysis simpler to understand without changing interpretation of the data overall.

**Response:** This point is very well taken. We agree that a cut off of 250g is arbitrary, however we could not find any literature supporting a different uterine weight to indicate advanced or difficult cases. Given the historical significance of this cutoff and the lack of clinical utility of a continuous



variable we chose to use the binary variable. For an additional sensitivity analysis, we also performed a categorical analysis of uterine weight as well as a subset analysis of only women small uteri.

**Change:** Lines 125- 130: “We tested uterine weight as a continuous, categorical (<250g, 250-499g, 500-100g and >1000g) and binary (<250g, ≥250g) variable. Modeling uterine weight in different ways resulted in little variation to the adjusted odds ratio and overall model fit. Ultimately, we chose to model uterine weight as a binary variable, either smaller or greater than 250 grams, as most clinicians are able to approximate uterine size as large or small, based on clinical exam prior to surgery and because 250 grams has been used as a benchmark for higher reimbursement, due to greater surgical complexity. <sup>20</sup>”

Lines 138-144: “Sensitivity analyses were performed to ensure our models were robust and sensitive to variations in how the uterine weight variable was categorized. First, given the large difference in median uterine weight of black versus white women, we limited our analysis to women with uterine weight less than 250g for both races to examine the possibility that uterine weight drives our adjusted analysis. “

Lines 164-166: “When the analysis was limited to only women with small uterine size (weight <250g), black women remained at significantly higher odds of undergoing open hysterectomy (aOR 1.84, 95%CI 1.61-2.11, supplemental table 1).”

**STATISTICAL EDITOR'S COMMENTS,** Comment 1. Table 1: parity can only have integer values. Should cite as median(IQR or range) and test non-parametrically. uterine wgt is often skewed. If non-normal distribution, should cite as median (IQR or range) and test non-parametrically.



**Response:** Parity is now described as an integer and uterine weight is presented as median with IQR and were tested with Kruskal Wallis rank sum test.

2. Tables 3 and 4: This is a large study, but the counts of adverse outcomes for major complications are relatively small in some subsets. It would be useful to complement the adjusted model analysis with matching (eg, propensity score matching), since there are so many significantly different baseline variables which potentially could affect outcomes.

**Response:** We agree that it is very important to consider the number of events when performing multivariable logistic regression. The smallest number of events was the major complications for the subset of women who underwent minimally invasive technique, which was almost 200. This allowed us to conservatively adjust for at least 10 different variables while still maintaining a stable model. However, we agree that additional modeling could only bolster the robustness of our statistical analysis. Therefore we created a propensity score matched cohort that matches the clinical characteristics of black and white women undergoing hysterectomy where all observed covariates are the same. The results have been added to table 4 and the characteristics of this cohort are described in supplemental data. The results of this analysis confirmed the stability of our estimates.

**Changes:** Lines 144-148: “Second, given that complications are rare events, in particular major complications, propensity score matching was undertaken to create a cohort where black and white subjects were balanced on the same factors accounted for in our logistic regression: prior abdominal surgery, prior pelvic surgery, endometriosis, BMI, age, comorbidities, procedures performed at the time of hysterectomy and, in our final analysis, route of hysterectomy (open versus minimally invasive).”



Lines 185-192: “In the propensity score matched cohort analysis there were no significant clinical differences that persisted after nearest neighbor matching (all p values >0.05) between the matched cohort of black and white women (supplemental table 2). Regression performed within this cohort largely confirmed the findings from the multivariable logistic regression: black women remained at increased odds of minor complications (OR 1.22, 95%CI 1.03-1.44) and increased odds of all complications (OR 1.25, 95%CI 1.08-1.46). However, in the matched cohort there was no difference in the odds of major complications for black versus white women when equally matched for uterine weight, prior abdominal surgery, pelvic surgery, endometriosis, BMI, age, comorbidity and additional procedures at time of hysterectomy.”

ASSOCIATE EDITOR-GYN'S COMMENTS:

1 - Please complement the adjusted model analysis with propensity score matching as suggested by the STAT Editor

**Response:** Thank you for the suggestion. We feel it bolsters the strength of our analysis. We described the changes made above.

2 - Rev #3 raises a common point which is the somewhat arbitrary cut-off of 250 gm when the clinician's presumption is that black women have much larger uteri than whites. For example, if blacks had huge uteri and whites were mainly 250-350 gm then this would not be analyze-able within their dataset and the whole argument would be inaccurate as the reason blacks need TAH more often is simple: they have much bigger uteri. One way of putting this to rest would be to compare the <250 gm pts: if there is a disparity there, then

it would serve as a reasonable proxy that there really is a disparity. The Discussion should speak to this point as well.

**Response:** Given that this was the main concern of several reviewers we have addressed this point in a variety of ways, included a sensitivity analysis including only women with uteri weight <250g. Additionally we explained our model selection further in our methods section.

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. 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.



Response: NSQIP is an administrative database. The validity of the database is described in the methods section, lines 99-104

3. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology 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>.

The definitions have been reviewed and only standard abbreviations are used.

4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 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).

Response: there are 2,445 words in the paper.

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

Response: The intro is 241 words. The discussion is 700 words.

5. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with the following guidelines:

\* All financial support of the study must be acknowledged.

Financial support is detailed on our cover sheet.

\* 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.

There was no manuscript preparation assistance.

\* 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 signature on the journal's author agreement form verifies that permission has been obtained from all named persons.

The authors have all signed an agreement.

\* 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).

The meeting (Society of Gynecologic Oncology) is provided.

6. 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, written in the present tense and stating 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."

The précis is present.

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.

Response: All numbers have been checked for accuracy. The word count is 262 words.

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.

Response: There are no abbreviations in the title or précis.

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.

Response: We have avoided this symbol.

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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

Response: The tables are compliant with this checklist.

## Daniel Mosier

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**From:** Emma Barber [REDACTED]  
**Sent:** Monday, October 1, 2018 10:16 PM  
**To:** Daniel Mosier  
**Subject:** Re: Manuscript Revisions: ONG-18-1468R1  
**Attachments:** Edited Manuscript 9-30-18 AA.docx

Dear Mr. Mosier,

Thank you for your edits and comments. We've made additional changes reflected in the attached file. Our response to your email is below:

Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.

Response: The minor changes, edits and deletions are appreciated. We agree with the changes.

LINE 1: Do you approve the edited title? Most of the title's subject was in the subtitle, so this was edited.

Response: Yes we agree with the edited title.

LINE 7: Please ask Jane Holl to respond to her authorship confirmation email. We emailed her at [REDACTED]  
[REDACTED] The email contains a link that needs to be clicked on. The sender of the email is [EM@greenjournal.org](mailto:EM@greenjournal.org)

Response: We have emailed Dr Holl, but the email in question may need to be resent. Would this be possible?

LINE 13: Please add the city and state of the meeting.

Response: Thank you for this suggestions, the city and state has been added.

LINE 34: Deletion of 2nd sentence allows Precis to get under word limit.

Response: Thank you for this correct, and we apologize for the oversight. We agree with the new wording.

LINE 38: Add the type of study you conducted to this section.

Response: Thank you. We have added the description of a cohort study to the abstract.

LINE 49: Based on Table 3, I've changed this to 4.1%. Is this correct?

Response: Yes, this is correct and we appreciate the change.

LINE 75: Add the type of study you conducted to this section.

Response: The type of study has been added

Change, Line 104: "A cohort study was performed using prospectively collected data. Patients"

LINE 80: Please add detail about why your study was exempt.

Response: This information has been added.

Change, Line 111: "The institutional review board at Northwestern University reviewed this study and deemed it exempt from formal review as all data previously existed and was also deidentified"

LINE 143: Please note the following regarding your tables:

- 1) Your tables should be cited in order at first mention.

Response: Thank you for this helpful comment, the tables have been renumbered and reordered as tables 1-6. Table 2 is in fact cited, as mentioned below.

- 2) Please incorporate the supplemental tables into the numbering of the other tables and call them "Table [number]." Your manuscript isn't overly long, so all tables can stay in print.

Response: Tables 1 and 2 remained table 1 and 2. Supplemental table 1 is now table 3. Tables 3 and 4 are now tables 4 and 5 respectively. Supplemental table 2 is now table 6. This has been corrected in the text of the manuscript.

- 3) There is an in-text citation missing for table 2.

Response: Thank you for this correction, it was initially identified as table 3, this has been corrected. The tables have been reordered.

- 4) The abstract and table 3 conflict

Response: The abstract initially said 4.0% and was corrected to 4.1%, as per table 3 (now table 4)

Thank you and please confirm receipt of these responses and the attached edited manuscript.

Thank you,

Emma Barber

On Fri, Sep 28, 2018 at 2:07 PM Daniel Mosier <[dmosier@greenjournal.org](mailto:dmosier@greenjournal.org)> wrote:

Dear Dr. Barber,

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 1: Do you approve the edited title? Most of the title's subject was in the subtitle, so this was edited.
3. LINE 7: Please ask Jane Holl to respond to her authorship confirmation email. We emailed her at [REDACTED]  
[REDACTED] The email contains a link that needs to be clicked on. The sender of the email is [EM@greenjournal.org](mailto:EM@greenjournal.org).
4. LINE 13: Please add the city and state of the meeting.
5. LINE 34: Deletion of 2nd sentence allows Precis to get under word limit.
6. LINE 38: Add the type of study you conducted to this section.
7. LINE 49: Based on Table 3, I've changed this to 4.1%. Is this correct?
8. LINE 75: Add the type of study you conducted to this section.
9. LINE 80: Please add detail about why your study was exempt.
10. LINE 143: Please note the following regarding your tables:

- 1) Your tables should be cited in order at first mention.
- 2) Please incorporate the supplemental tables into the numbering of the other tables and call them "Table [number]." Your manuscript isn't overly long, so all tables can stay in print.
- 3) There is an in-text citation missing for table 2.

Currently, the tables are numbered in this order:

Table 1

Table 3

Supplemental Table 1

Table 4

Supplemental Table 2

You will need to renumber and reorder your tables.

11. TABLE 2: There is an in-text citation missing for Table 2.
12. TABLE 3: Abstract says 4.0%.

Each of these points are marked in the attached manuscript. Please respond point-by-point to these queries in a return email, and make the requested changes to the manuscript. When revising, please leave the track changes on, and do not use the “Accept all Changes” function in Microsoft Word.

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Tuesday, October 2nd**.

Sincerely,

-Daniel Mosier

**Daniel Mosier**

Editorial Assistant

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