

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)*
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obgyn@greenjournal.org.

Date: Jan 04, 2019
To: "Emma Longley Barber" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-2241

RE: Manuscript Number ONG-18-2241

Cystoscopy at the time of benign hysterectomy and delayed lower genitourinary tract injury

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 Jan 25, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

Authors sought to compare the rate of lower genital tract injury occurring between days 1-30 post hysterectomy for benign indications in women who had cystoscopy versus those who did not at the time of surgery using NQIP database. They reported no differences in rate.

1. The rationale for the study is uncertain given a large body of evidence showing cystoscopy at the time of hysterectomy does not reduce the incidence of diagnosis of delayed genito-urinary injuries.
2. The NSQIP database may not be the appropriate resource to study this question because of the potential for selection bias. It is unclear if surgeons or practices that perform cystoscopy do them routinely or they selectively perform cystoscopy in particular cases considered to be at risk for injury. Therefore, true differences between the practices of routine cystoscopy versus not may be masked. Alternatively, it may show differences if the practice is highly selective as it did in the cohort that underwent open surgery.
3. If the real question is to determine incremental benefit of cystoscopy in reducing the rate of delayed diagnosis of ureteric/bladder injuries, then all cases including those diagnosed intra-operatively (via cystoscopy) should be included in the analyses.
4. Overall, very well written manuscript.

REVIEWER #2:

1. Methods: the authors state that delayed urinary injury was defined as reoperation for urinary track injury, as well as NSQIP definition. Please confirm that included in this definition are interventions such as stent placement, nephrostomy, or prolonged Foley placement (ie not just an operative intervention).
2. Please define benign hysterectomy - does this include hysterectomy for pelvic organ prolapse or combined with other urogynecologic procedures? Although procedures performed by Urogynecologists were excluded, it is not unusual for generalists to perform these procedures. This is important given the ACOG recommendations around cystoscopy. I completely agree cystoscopy is not necessary for benign hysterectomy, but may have a favorable risk benefit ratio for POP.

3. It may be of interest to the reader to know what postoperative day the urinary injuries were diagnosed. Please add these data as they were collected as stated in Methods.

4. The authors correctly point out that performing cystoscopy is at the discretion of the surgeon, and that its limitations should be acknowledged given the fact that urinary injuries were nevertheless identified in patients undergoing cystoscopy. This is an important point and the authors may wish to expand on this message and recommend that intraoperative consultation or prophylactic stent placement be performed if a urinary track injury is suspected, as cystoscopy cannot definitely rule out these conditions as described.

REVIEWER #3:

This manuscript compares the rate of 30-day delayed lower GU injury recognition in benign hysterectomy for those women who underwent intraoperative cystoscopy vs those who didn't. Sample size is >43000 women in the 2015-2017 NSQIP database. The authors acknowledge that these data come from only certain hospitals that voluntarily report, thus they may not be generalizable to the population as a whole. The authors conclude that there is no benefit to routine intraoperative cystoscopy for the primary outcome of delayed GU tract injury. This is very likely true, but it ignores why most intraoperative cystoscopy is done: to assist the surgeon in ruling out intraoperative GU injury while something can still be done about it under the same anesthetic. Many studies show the advantage of cystoscopy following complex benign gyn surgery, and at least several have shown statistical advantage after benign hysterectomy, even when done routinely. Clearly, most GU injuries are noticed at the time of the cystoscopy itself, or well before 30 days post-op, and those that aren't noticed until 30+ days out comprise a significantly smaller subset, probably accounting for the results of this study. These latter, delayed injuries would primarily be thermal injuries that incompletely damage the ureter or bladder, leaving them invisible to the cystoscopist.

The authors also exclude any gyn operation other than benign hysterectomy alone, and then allow consideration only of those performed by a general, non-subspecialist gynecologist. This, of course, will underestimate the utility of cystoscopy in other benign hysterectomies, perhaps where adnexal surgery was also required, and will underestimate its usefulness to other gynecologic surgeons (e.g. low-volume gynecologists such as MFMs doing cesarean hysterectomies, or REIs who likely do fewer hysterectomies than generalists).

The paper tends to be wordy and repetitive, but the subject matter is currently under spirited debate, and this manuscript will probably add some useful information to the discussion, despite its narrow scope.

STATISTICAL EDITOR'S COMMENTS:

1. Table 3: While it is true that there were no statistically different rates of any or individual types of lower GU tract injury for the cystoscopy vs no cystoscopy cohorts, the rates of such injury were very low. The rarity of these events dictates the low statistical power in generalizing the NS result. Given the rates of injury, the two population cohorts at risk and their relative sizes, the alternative incidence (compared to the no cysto cohort of 0.24%) would have to be < .10% or > 0.40% to conform to the usual criteria of 80% power and $\alpha < .05$. That is, the study result is negative, but with low statistical power to generalize. That issue is compounded in the analysis by type of injury, with rarer rates of injury.

2. In addition, from Table 1, there were baseline differences that are not adjusted for in Table 3.

3. Table 4: Since this was not the primary outcome, but rather subset analysis of injury, these comparisons would require a stricter inference threshold, since there are now 3 hypotheses tested. Again, are there any relevant baseline differences that have not been adjusted for?

4. Table 5: The NS difference for delayed lower GU injury again has low power to generalize. There are sufficient numbers and sufficient differences to affirm the difference in UTI rates and OR times

EDITORIAL OFFICE COMMENTS:

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3. 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.

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

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

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

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12. 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.

13. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at <https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance>.

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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 Jan 25, 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

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



January 7th, 2019

Dear Editors of Obstetrics and Gynecology,

Please find the revisions to our manuscript entitled “Cystoscopy at the time of benign hysterectomy and delayed lower urinary tract injury”. We appreciate the opportunity to revise and resubmit our work.

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

We have followed the STROBE Guidelines for this submission.

We appreciate the opportunity to submit our work and look forward to hearing from you.

Yours sincerely,

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

Emma Longley Barber, MD, MS



REVIEWER COMMENTS:

REVIEWER #1:

Authors sought to compare the rate of lower genital tract injury occurring between days 1-30 post hysterectomy for benign indications in women who had cystoscopy versus those who did not at the time of surgery using NQIP database. They reported no differences in rate.

Reviewer #1, Comment #1: The rationale for the study is uncertain given a large body of evidence showing cystoscopy at the time of hysterectomy does not reduce the incidence of diagnosis of delayed genito-urinary injuries.

Reviewer #1, Response #1: We appreciate the reviewer's clarity about this topic and happen to agree. However, as noted by other reviewers (reviewer 3), by the debate at the ACOG annual meeting (reference 11), and by reference 9, there is some published evidence that cystoscopy may decrease delayed genitourinary injuries and many institutions and surgeons have pursued a policy of universal cystoscopy for this reason. Therefore, we respectfully disagree that this is a settled question in the current literature. We have tried to frame the introduction to address the two sides of this argument.

Lines 124-128 "At the University of Michigan, implementation of a universal cystoscopy policy at the time of benign hysterectomy performed by benign gynecologists was associated with a significant decrease in delayed postoperative urologic complications (7 injuries, 0.7% 95% CI 0.3-1.2% pre-implementation vs 2 injuries, 0.1% 95% CI 0.0-0.3% post-implementation).⁹ ... Larger studies, however, have not corroborated this finding. A systematic review and meta-analysis that included 79 studies with 41,482 hysterectomies found that universal cystoscopy did not decrease the incidence of delayed genitourinary injuries.¹⁰ ... Given the conflicting reports in the literature regarding the benefits of cystoscopy in decreasing the incidence of delayed genitourinary injuries, further research into the best application of cystoscopy to benign hysterectomy is needed to inform quality and practice guidelines.¹¹"

Reviewer #1, Comment #2: The NSQIP database may not be the appropriate resource to study this question because of the potential for selection bias. It is unclear if surgeons or practices that perform cystoscopy do them routinely or they selectively perform cystoscopy in particular cases considered to be at risk for injury. Therefore, true differences between the practices of routine cystoscopy versus not may be masked. Alternatively, it may show differences if the practice is highly selective as it did in the cohort that underwent open surgery.

Reviewer #1, Response #2: We agree with the reviewer that the question of universal versus selective cystoscopy cannot be answered with this data source.



Therefore, we have framed our objective as “The objective of this study was to estimate the association between cystoscopy at the time of benign hysterectomy and the subsequent occurrence of a delayed genitourinary tract injury.” Not to assess differences in universal versus selective cystoscopy approaches.

Additionally, we have discussed this limitation in the discussion, lines 335-342.

“The policies and surgical practice patterns regarding cystoscopy for these institutions and surgeons are unknown and thus the debate regarding universal versus selective cystoscopy cannot be resolved with these data.”

Reviewer #1, Comment #3: If the real question is to determine incremental benefit of cystoscopy in reducing the rate of delayed diagnosis of ureteric/bladder injuries, then all cases including those diagnosed intra-operatively (via cystoscopy) should be included in the analyses.

Reviewer #1, Response #3: For universal cystoscopy to be an effective screening tool, it has to not only diagnose a genitourinary injury but prevent the occurrence of a delayed injury.

We have made the following changes to attempt to clarify within the introduction why the truly relevant outcome of interest is delayed genitourinary injury. Lines 139-142. “Although cystoscopy is done at the conclusion of the surgery and thus cannot prevent the lower genitourinary tract injury itself, cystoscopy aims to recognize the injury intra-operatively and therefore convert injuries that would have been delayed and unrecognized to injuries that are recognized and fixed at the time of hysterectomy. Therefore, if cystoscopy is a useful sufficiently sensitive screening tool for the diagnosis of unrecognized genitourinary tract injury at the time of hysterectomy, women who undergo cystoscopy should have a lower risk of a subsequent delayed genitourinary tract injury compared to women who do not undergo cystoscopy as the cystoscopy would result in detection and repair.”

Additionally, the rate of intraoperative injury cannot be estimated with this data source as cystoscopy is universally used intra-operatively in cases where a ureteral injury is recognized (whether it has been used to recognize the injury or only afterwards to evaluate the repair) as cystoscopy is used to examine the integrity of the repair.

Reviewer #1, Comment #4: Overall, very well written manuscript.

Reviewer #1, Response #4: We thank the reviewer for this comment.

REVIEWER #2:



Reviewer 2, Comment 1: Methods: the authors state that delayed urinary injury was defined as reoperation for urinary track injury, as well as NSQIP definition. Please confirm that included in this definition are interventions such as stent placement, nephrostomy, or prolonged Foley placement (ie not just an operative intervention).

Reviewer 2, Response 1: We thank the reviewer for this comment. We have clarified that non-operative interventions are included in the NSQIP definitions.

Lines 172-175. "As these complications are collected from direct medical record review, non-surgical treatment, such as percutaneous nephrostomy tube placement or catheter placement to treat a genitourinary tract injury, are included."

Reviewer 2, Comment 2: Please define benign hysterectomy - does this include hysterectomy for pelvic organ prolapse or combined with other urogynecologic procedures? Although procedures performed by Urogynecologists were excluded, it is not unusual for generalists to perform these procedures. This is important given the ACOG recommendations around cystoscopy. I completely agree cystoscopy is not necessary for benign hysterectomy, but may have a favorable risk benefit ratio for POP.

Reviewer 2, Response 2: This is an excellent point. Given the ACOG recommendations regarding universal cystoscopy in POP procedures, all hysterectomies performed with CPT codes for incontinence or prolapse procedures were excluded. This language has been added to the methods and the codes to define this group added to Appendix 1.

Abstract, Lines 63-64. "Patients who underwent hysterectomy without a concomitant procedure for prolapse or incontinence for benign pathology"

Methods, lines 173-176: "Hysterectomy with additional procedures performed to treat prolapse and urinary incontinence, as defined by CPT code (Appendix 1) were also excluded, again given the clear guidelines for cystoscopy in this population due to the higher rate of urinary tract injury."

Reviewer 2, Comment 3: It may be of interest to the reader to know what postoperative day the urinary injuries were diagnosed. Please add these data as they were collected as stated in Methods.

Reviewer 2, Response 3: We agree with the reviewer that this is an interesting point. We have also compared the day the injuries were diagnosed in Table 3 and referenced these results in the methods.

Lines 246-247. "Additionally, the median postoperative day the injury was diagnosed was not statistically different between patients who underwent cystoscopy and those who did not (Table 3)."

Reviewer 2, Comment 4: The authors correctly point out that performing cystoscopy is at the



discretion of the surgeon, and that its limitations should be acknowledged given the fact that urinary injuries were nevertheless identified in patients undergoing cystoscopy. This is an important point and the authors may wish to expand on this message and recommend that intraoperative consultation or prophylactic stent placement be performed if a urinary track injury is suspected, as cystoscopy cannot definitely rule out these conditions as described.

Reviewer 2, Response 4: We have changed the discussion to incorporate this suggestion.

Lines 328-331. "Consideration for an intraoperative consultation or prophylactic stent placement may be warranted if there is a suspicion of genitourinary tract injury, even if cystoscopy is normal, as it cannot definitively rule out these conditions."

REVIEWER #3:

Reviewer #3, Comment #1: This manuscript compares the rate of 30-day delayed lower GU injury recognition in benign hysterectomy for those women who underwent intraoperative cystoscopy vs those who didn't. Sample size is >43000 women in the 2015-2017 NSQIP database. The authors acknowledge that these data come from only certain hospitals that voluntarily report, thus they may not be generalizable to the population as a whole. The authors conclude that there is no benefit to routine intraoperative cystoscopy for the primary outcome of delayed GU tract injury. This is very likely true, but it ignores why most intraoperative cystoscopy is done: to assist the surgeon in ruling out intraoperative GU injury while something can still be done about it under the same anesthetic. Many studies show the advantage of cystoscopy following complex benign gyn surgery, and at least several have shown statistical advantage after benign hysterectomy, even when done routinely. Clearly, most GU injuries are noticed at the time of the cystoscopy itself, or well before 30 days post-op, and those that aren't noticed until 30+ days out comprise a significantly smaller subset, probably accounting for the results of this study. These latter, delayed injuries would primarily be thermal injuries that incompletely damage the ureter or bladder, leaving them invisible to the cystoscopist.

Reviewer #3, Response #1: We have clarified in the introduction why delayed genitourinary injury is the outcome of interest. An increase in intra-operative detection without a subsequent decrease in delayed genitourinary injury rates calls into question the true clinical benefit of cystoscopy.

We have attempted to clarify this logic in the introduction.

Lines 139-147. "Although cystoscopy is done at the conclusion of the surgery and thus cannot prevent the lower genitourinary tract injury itself, cystoscopy aims to recognize the injury intra-operatively and therefore convert injuries that would have been delayed and unrecognized to injuries that are recognized and fixed at the time of hysterectomy. Therefore, if cystoscopy is a useful sufficiently sensitive screening tool for the diagnosis of unrecognized genitourinary tract injury at the



time of hysterectomy, women who undergo cystoscopy should have a lower risk of a subsequent delayed genitourinary tract injury compared to women who do not undergo cystoscopy as the cystoscopy would result in detection and repair.”

Reviewer #3, Comment #2: The authors also exclude any gyn operation other than benign hysterectomy alone, and then allow consideration only of those performed by a general, non-subspecialist gynecologist. This, of course, will underestimate the utility of cystoscopy in other benign hysterectomies, perhaps where adnexal surgery was also required, and will underestimate its usefulness to other gynecologic surgeons (e.g. low-volume gynecologists such as MFMs doing cesarean hysterectomies, or REIs who likely do fewer hysterectomies than generalists).

Reviewer #3, Response #2: We apologize that the cohort of patients was not clear from our language. Hysterectomies with additional procedures (except those to treat prolapse and urinary incontinence) were included. The methods have been clarified to highlight this. The sensitivity analysis and operative time analysis included only benign hysterectomy alone.

Lines 177-178 “Hysterectomies with additional procedures performed that were not directed at prolapse or incontinence were included.”

Lines 203-207. “To isolate the operative time attributable to cystoscopy alone, patients with only a hysterectomy CPT code (Appendix 1) and a diagnostic cystoscopy code (CPT 52000) were compared to patients with only a hysterectomy code to eliminate operative time that could be explained by the time required to perform additional procedures.”

Reviewer #3, Comment #3: The paper tends to be wordy and repetitive, but the subject matter is currently under spirited debate, and this manuscript will probably add some useful information to the discussion, despite its narrow scope.

Reviewer #3, Response #3: We thank the reviewer for this comment.

STATISTICAL EDITOR'S COMMENTS:

Statistical Editor, Comment #1: Table 3: While it is true that there were no statistically different rates of any or individual types of lower GU tract injury for the cystoscopy vs no cystoscopy cohorts, the rates of such injury were very low. The rarity of these events dictates the low statistical power in generalizing the NS result. Given the rates of injury, the two population cohorts at risk and their relative sizes, the alternative incidence (compared to the no cysto cohort of 0.24%) would have to be $< .10\%$ or $> 0.40\%$ to conform to the usual criteria of 80% power and $\alpha < .05$. That is, the study result is negative, but with low statistical power to generalize. That issue is compounded in the analysis by type of injury, with rarer rates of injury.



Statistical Editor, Response #1: We agree that this is true. However, aside from a systematic review and meta-analysis, all of the published and highly cited publications on this topic are significantly smaller and thus with similar or lower statistical power. Nevertheless, we believe it prudent to highlight the difference in rates that would be required to show a difference with this sample size. We have made the following changes.

Lines 384-388. “Finally, although we had a large sample size, delayed genitourinary injuries were rare and thus the ability to adjust for confounders or to have sufficient power to detect a small benefit to cystoscopy (smaller than magnitude 0.16%) was limited, however, as can be seen in Tables 1 and 2, clinical differences to suggest confounding were rare.”

Statistical Editor, Comment #2: In addition, from Table 1, there were baseline differences that are not adjusted for in Table 3.

We agree that baseline differences are noted in Table 1. However, given the small sample size, and the rarity of injuries, multivariable adjustment beyond 3-4 variables would likely lead to instability of the multivariable model. We have discussed this in the discussion. Additionally, although there are statistically significant differences in Table 1, this is likely secondary to the large sample size – the clinical differences are minimal.

Lines 384-388. “Finally, although we had a large sample size, delayed genitourinary injuries were rare and thus the ability to adjust for confounders or to have sufficient power to detect a small benefit to cystoscopy (smaller than magnitude 0.16%) was limited, however, as can be seen in Tables 1 and 2, clinical differences to suggest confounding were rare.”

Statistical Editor, Comment #3: Table 4: Since this was not the primary outcome, but rather subset analysis of injury, these comparisons would require a stricter inference threshold, since there are now 3 hypotheses tested. Again, are there any relevant baseline differences that have not been adjusted for?

We agree that multiple hypothesis testing is a concern here. However, given our use of a composite outcome, we simply wanted to show the reader that there were not marked differences between the two groups with regard to each subgroup. We provided a p-value out of convention and because we anticipated readers would expect to see it, but could also remove the p-values from the table if the statistical reviewer and editors feel hypothesis testing is not appropriate here.

Statistical Editor, Comment #4: Table 5: The NS difference for delayed lower GU injury again has low power to generalize. There are sufficient numbers and sufficient differences to affirm the difference in UTI rates and OR times



We agree with this. We have performed the relevant power calculation for the sensitivity analysis as well.

We have added the following to the discussion:

Lines 384-387. "Finally, although we had a large sample size, delayed genitourinary injuries were rare and thus the ability to adjust for confounders or to have sufficient power to detect a small benefit to cystoscopy (smaller than magnitude 0.16% or 0.18% for the sensitivity analysis) was limited."

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.

Yes, we OPT IN for this.

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.



Understood, co-authors will await the email.

3. 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.

This information is noted in paragraph one of the methods.

Lines 153-164. “A cohort study of women who underwent hysterectomy for benign indications recorded in the National Surgical Quality Improvement Program (NSQIP) was performed. The National Surgical Quality Improvement Program is a national quality database that collect preoperative, intraoperative and postoperative variables related to surgical procedures. Hospitals voluntarily participate in the database, and in exchange for participation, are given data regarding their own procedures to drive quality improvement.¹² Data are abstracted by trained clinical reviewers and are audited regularly. For an institution’s data to be used in the nationally available file, the interobserver agreement during the audit must be greater than 95% and averages 98% for included sites.¹³ Within NSQIP, there is a targeted hysterectomy file that includes patient history, intraoperative, and postoperative variables specific to hysterectomy.¹⁴”

4. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), 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.



We have followed the STROBE guidelines and have submitted a checklist.

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

This is not a problem.

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

Our manuscript meets these criteria.

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).

We have included all of this information on the title page.



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

We have added this, line 24.

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.

We have reviewed the abstract. The word count is less than 300 words.

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.

We have not used non-standard abbreviations.

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.

We have not used this symbol.

12. 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.



We have reviewed this and our tables are in this format.

13. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at <https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance>.

We have confirmed this.

14. 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>.

We decline to publish this manuscript open access.

Daniel Mosier

From: Emma Barber [REDACTED]
Sent: Friday, January 25, 2019 3:36 PM
To: Daniel Mosier
Subject: Re: Manuscript Revisions: ONG-18-2241R1
Attachments: 18-2241R1 ms (1-25-19v2) EB 1 25 19.docx

Hello Mr Mosier,

Attached is the revised manuscript with the changes suggested listed in track changes.

Please let me know if you have any questions. I believe I responded to all queries.

Thank you in advance for your consideration.

Emma Barber

On Fri, Jan 25, 2019 at 1:46 PM Daniel Mosier <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 63: Add the type of study you conducted to this section.
3. LINE 79: This p-value was added to line 270.
4. LINE 129: Please insert Refs from line 103 here.
5. LINE 260: Added from abstract.
6. LINE 342: Please note, a title was added.

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, January 29th**.

Sincerely,

-Daniel Mosier

Daniel Mosier

Editorial Assistant

Obstetrics & Gynecology

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