RE: Manuscript Number ONG-19-385

Urologic Injury and Fistula Following Hysterectomy for Benign Indications

Dear Dr. Dallas:

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

REVIEWER COMMENTS:

Reviewer #1: Dallas and colleagues examined the rate of ureteral and bladder injuries after hysterectomy. Comments for the authors:

Overall

1. The rate of ureteral injury was nearly 50% higher than bladder injury. There is a large body of literature suggesting the opposite is true. This likely indicates difficult with accurate case ascertainment from the database.

Abstract

2. 95% confidence intervals should be used with the odds ratios if possible.

3. The percentage of cases in which bladder or ureteral injuries occurred should be included.

Introduction

4. Line 157 likely “re” operation?

5. Would be helpful to define the specific rates of injury along with fistula rates from the literature.

Methods

6. Is data on outpatient follow-up available? Presumably some patients may have delayed recognition of a fistula that healed with conservative management?

Results

7. Seems unusual that 93% of patients were outpatient procedures yet 37% had an abdominal hysterectomy?

8. Were obstetric hysterectomies included?

9. Might be interesting to breakdown the timing of the delayed repair cases a bit more.

Discussion
10. Overall well written with acknowledgement of limitations

Reviewer #2: Thank you for doing a deep dive into a very dicey topic! Your paper is novel because you separate delayed identification vs immediate identification of lower urinary tract injury. The long follow-up 2005-2011 using this Statewide Database is also important. I think the introduction, methods and discussion are very well written and referenced.

RESULTS:
1) Can you please mention what percent of the total 296,130 patients had cystoscopy done at the time of the abdominal, laparoscopic, vaginal and LAVH procedures? Similarly, what percent of the patients with delayed injuries had a cystoscopy at the time of the initial surgery. The paper discusses stent placement but this basic piece of information is missing from the manuscript. Figure 1 is the money shot, and I think an interesting corollary for discussion is reviewing those patients with delayed identification of injuries, who actually also had intra-operative cystoscopy. Of course the surgeon could have mistakenly missed an injury that was present (e.g. hole in bladder trigone, stitch in bladder, lack of efflux from a ureter) but delayed injuries purportedly occur due to thermal injury and tissue necrosis. I know that we would be asking you to separate details even more than the way you have already laid out in this manuscript, but this one more data point has clinical practice significance.

2) Concomitant prolapse and incontinence surgery at the time of hysterectomy makes your analysis more complicated. Although the numbers are small, what percent of cystotomy injuries were at the time of the anti-incontinence procedures? A small cystotomy at the time of a synthetic sling placement happens frequently (up to 10% if learners involved) but has no real long-term sequelae. But an injury to the trigone at the time of hysterectomy or vaginal mesh placement is a completely different story. Is there any way to tease this out--location matters (dome vs trigone)--because for future fistula formation, location, location, location really matters.

3) Delayed or unidentified injuries are what lead most to litigation, as you mention. A thermal injury related to endometriosis surgery that results in a uretero-vesicovaginal fistula is much more defensible when a normal cystoscopy was done at the time of the original surgery than a ureterovesical fistula that develops postoperatively and no cystoscopy was performed. Can you break this down more, understanding that cystotomy at the dome or telescope using a lighted scope are other options to intraoperatively evaluate ureteral and bladder integrity.

Reviewer #3:
1. Do you have any information on the surgeons who performed these cases or is the identification limited to the hospital? It seems more likely that urinary tract injury would be related to low volume surgeons rather than low volume hospitals. While it is probably true that lower volume hospitals will have lower volume surgeons, it would be interesting to know the rate of complications related to individual surgeon case volume.

2. Is there any information available on whether a cystoscopy was performed at the time of hysterectomy?

3. How are cases converted from one approach to another handled? For example, a case converted from vaginal or laparoscopic to open? If you code these as open, you may falsely increase the rate of complications with open cases if, for example, the injury occurred during the first part of the case. You could look at your data based on intention to treat. This could help reduce the possibility of making the open approach seem more morbid than it actually would be if not used to salvage difficult vaginal or laparoscopic cases- possibly where a urinary tract injury has already occurred.

4. How do you define "mesh placed"- is this strictly vaginal mesh placed for prolapse or does it include sacrocolpopexy mesh, midurethral slings?

5. Since the data is from 2005 to 2011, do you think there might be any difference if the data from more recent years was examined?

6. Black race was protective but Asians were at higher risk for urinary tract injury (table 3). How can these differences be explained?

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

lines 56-63: Should re-organize this section. First, the n(%) for ≥1 GU injury should be cited overall and for the immediate vs delayed cohorts. Second, the rates of fistula formation among those subsets should be cited as n(%) for bladder, ureteral and combined, contrasting the immediate vs delayed groups. Finally, the figures cited on line 59 are not consistent with Fig 1. The rate of bladder fistula formation was 43/1789 (2.3%) vs 4/95 (4.2%) which had p = .28. The rates for ureteral fistulae were 14/2214 (0.6%) vs 10/429 (2.3%), with p < .001. The fistula rates for combined were 6/162 (3.7%) vs 3/12 (25%), with p = .002.

Would also be informative to cite rates of GU injury and fistula formation as incidence per 1000 women, with CIs to put findings in context.

Also, since the study was observational, with either stent or operative repair for ureteral or combined injuries, should either attempt to adjust for that difference and/or acknowledge that difference in surgical approach for immediate vs delayed cohorts might have affected subsequent rates of fistula formation.

Tables 1, 2: Suggest separating the p-values into a separate column and more explicitly identifying the referent groups. Also, need to enumerate all missing values, since some of the individual characteristic totals do not equal the sums cited for total or injury columns.

Table 3: Since this is a multivariate model, should have separate column(with CI) for crude, then adjusted ORs.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor’s specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

***The notated PDF is uploaded to this submission’s record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.***

- We do not require that initial submissions adhere to the Green Journal publication requirements. Articles for which a revision is requested however, do require that the revised submission adhere to all Green Journal formatting requirements. We strongly recommend that you read the Instructions for Authors to be able to present your revised submission in a format that is likely to allow for a prompt final decision. For instance, the Key Points here are not part of our journal features.

- The objective for the abstract should be a simple "to" statement without background.

- In both the abstract and the paper, please provide absolute numbers as well as which ever effect size you are reporting (if appropriate) + Confidence intervals. P values may be omitted for space concerns. We strongly prefer CI's as they give more information about strength of association than do P values. By absolute values, I mean something like xx (outcome in exposed)/yy (outcome in unexposed) (zz%) (Effect size= ; 95% CI=. ) An example might be: Outcome 1 was more common in the exposed than the unexposed 60%/20% (Effect size=3;95% CI 2.6-3.4).

- Please consult the Instructions for Authors regarding the use of abbreviations, and what constitutes an acceptable abbreviation. This is not an acceptable abbreviation. Please spell out all abbreviations on first use. It is reasonable to not use abbreviations for words that are seldom used in the paper. We try to limit “unique” abbreviations so that readers don’t have to frequently refer back to the first notation of the abbreviation to remember its meaning. We realize that this may affect word count but believe it makes it easier in most cases for the reader.

- It is not clear if this 834 is part of the 4800 approximate ureteral and bladder injuries, or are they 3rd group?

- Please note that effect sizes (RR, OR) within the zone of potential bias should be noted as weak. Those effect sizes in the zone of potential interest should be emphasized. (Ref: False alarms and pseudo-epidemics. The limitations of observational epidemiology. Grimes DA, Schulz KF. Ob Gyn 2012;120:920-7). In the discussion section of your paper, please address this as a limitation.

- you can drop the "often" since you give the % of time they are unrecognized.

- please delete the colon and the a), b) and c)’s. you can separate the 3 choices by a comma. Please also avoid single sentence paragraphs.
- Please provide information regarding how these databases are validated for accuracy. Since your study is based on clinical coding, is it known how accurately the databases reflect the true CPT and ICD-9 (or 10) codes for what was done?

- The Journal style doesn’t not use the virgule (/) except in numeric expressions. Please edit here and in all instances.

- see note above re:abbreviation use

- This is called a primacy claim: yours is the first, biggest, etc...In order to assert that, you need to provide the search terms used and the data base(s) searched (PubMed,Google Scholar, etc) to substantiate the claim. Otherwise, it needs to be deleted. It wouldn’t belong in the abstract anyway, so make sure you address this in the manuscript body.

- Since it seems your study confirms prior studies, what makes it distinct? What new findings does it add?

- I don’t think "less minimally invasive" applies to open hysts. Minimally invasive refers to other means but one would never consider an open case even minimally minimally invasive.

- Make sense here to perhaps mention which GU tract injuries would likely be missed with universal cysto, such as thermal injuries.

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

- again, as all of your OR’s are > 1 and < 2.00 or. < 1 and > 0.3, please make sure you comment on the zone of potential bias.

2. 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:
   a. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
   b. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

3. 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.

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

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

5. 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.

6. Please submit a completed STROBE checklist.

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.

7. 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.

8. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendices) but exclude references.


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).

10. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

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

12. 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.

13. 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.

14. 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.

15. Line 306-309: We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

16. 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.

17. 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 (i.e., 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 (e.g., 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.

18. When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file). Please recheck your arithmetic in Figure 1 to make sure it is correct.

19. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acd/accounts/ifauth.htm.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

20. If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Apr 25, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r) Please contact the publication office if you have any questions.
April 17th, 2019  
Dr. Nancy C. Chescheir, MD  
Editor-in-Chief, *Obstetrics & Gynecology*

Dr. Chescheir,

We appreciate the opportunity to revise our manuscript for continued exclusive consideration for publication as an article in *Obstetrics & Gynecology*. Please see the response to the reviewers included in this document.

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

In addition, I attest that the STROBE guidelines have adhered to, and a completed checklist is included with this cover letter.
STROBE Statement—checklist of items that should be included in reports of observational studies

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
<th>Page No</th>
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<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1</td>
<td>(a) Indicate the study’s design with a commonly used term in the title or the abstract</td>
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<td>(b) Provide in the abstract an informative and balanced summary of what was done and what was found</td>
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<td><strong>Introduction</strong></td>
<td>2</td>
<td>Explain the scientific background and rationale for the investigation being reported</td>
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<td><strong>Objectives</strong></td>
<td>3</td>
<td>State specific objectives, including any prespecified hypotheses</td>
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<td><strong>Methods</strong></td>
<td>4</td>
<td>Present key elements of study design early in the paper</td>
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<td>Study design</td>
<td>4</td>
<td>Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection</td>
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<td>Setting</td>
<td>5</td>
<td>Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</td>
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<td>Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</td>
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<td>Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants</td>
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<td>Participants</td>
<td>6</td>
<td>(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed</td>
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<td>Variables</td>
<td>7</td>
<td>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</td>
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<tr>
<td>Data sources/measurements</td>
<td>8*</td>
<td>For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group</td>
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<td>Bias</td>
<td>9</td>
<td>Describe any efforts to address potential sources of bias</td>
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<td>Study size</td>
<td>10</td>
<td>Explain how the study size was arrived at</td>
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<td>Quantitative variables</td>
<td>11</td>
<td>Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why</td>
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<td>Statistical methods</td>
<td>12</td>
<td>(a) Describe all statistical methods, including those used to control for confounding</td>
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<td>(b) Describe any methods used to examine subgroups and interactions</td>
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<td>(c) Explain how missing data were addressed</td>
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<td>(d) <strong>Cohort study</strong>—If applicable, explain how loss to follow-up was addressed</td>
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<td><strong>Case-control study</strong>—If applicable, explain how matching of cases and controls was addressed</td>
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<td><strong>Cross-sectional study</strong>—If applicable, describe analytical methods taking account of sampling strategy</td>
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<td>(e) Describe any sensitivity analyses</td>
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### Results

<table>
<thead>
<tr>
<th>Participants</th>
<th>13*</th>
<th>(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed</th>
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<td>(b) Give reasons for non-participation at each stage</td>
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<td>(c) Consider use of a flow diagram</td>
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<td>Descriptive data</td>
<td>14*</td>
<td>(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders</td>
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<td>(b) Indicate number of participants with missing data for each variable of interest</td>
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<td>(c) <em>Cohort study</em>—Summarise follow-up time (eg, average and total amount)</td>
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<td>7-8, Table 1</td>
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<td>Outcome data</td>
<td>15*</td>
<td><em>Cohort study</em>—Report numbers of outcome events or summary measures over time</td>
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<td><em>Case-control study</em>—Report numbers in each exposure category, or summary measures of exposure</td>
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<td></td>
<td><em>Cross-sectional study</em>—Report numbers of outcome events or summary measures</td>
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<td>Main results</td>
<td>16</td>
<td>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included</td>
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<td>(b) Report category boundaries when continuous variables were categorized</td>
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<td>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period</td>
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<tr>
<td>Other analyses</td>
<td>17</td>
<td>Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses</td>
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### Discussion

<table>
<thead>
<tr>
<th>Key results</th>
<th>18</th>
<th>Summarise key results with reference to study objectives</th>
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<tbody>
<tr>
<td>Limitations</td>
<td>19</td>
<td>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</td>
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<tr>
<td>Interpretation</td>
<td>20</td>
<td>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</td>
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<tr>
<td>Generalisability</td>
<td>21</td>
<td>Discuss the generalisability (external validity) of the study results</td>
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</table>

### Other information
Funding

Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

REVIEWER COMMENT RESPONSES:

Reviewer #1: Dallas and colleagues examined the rate of ureteral and bladder injuries after hysterectomy. Comments for the authors:

Overall

1. The rate of ureteral injury was nearly 50% higher than bladder injury. There is a large body of literature suggesting the opposite is true. This likely indicates difficult with accurate case ascertainment from the database.

**We found an overall ureteric injury rate of 1.0% and bladder injury rate of 0.7%. These rates are largely consistent with existing literature.**

**Reported rates in the literature rang from 0.03–1.5% for ureteric injury and 0.2–1.8% for bladder injuries (1-4).**

**A prospective study by Ibeanu et al found a ureteric injury rate of 1.7% in total abdominal hysterectomy and 2.6% in transvaginal hysterectomy.**

**That being said, the 0.7% rate of bladder injury reported did NOT include those patients who developed a fistula without any reported injury (0.3%). When considering the fact that most of these fistulas involved the bladder, our bladder injury rate (0.7% + 0.3%) is almost identical to the ureteral injury rate Another important point is that the rate of ureteral injury we report is likely somewhat overestimated given that some stents may have been placed due to “suspicion” of an injury, without a true injury occurring. Unfortunately, there is no way to definitively know which cases involved a true injury as we have already included in the manuscript.**
Additionally, we report in the manuscript that in the cases of identified-immediate injuries managed with an indwelling stent alone, a diagnosis code of a ureteral injury was only present in 332 cases (18.7%) which suggests how potentially unreliable diagnosis codes may be in instances like this. If we only included these patients, the overall ureteral injury rate would be 0.5%. It is important to keep in mind however, that even in cases of formal operative repair of the ureter, a diagnosis of a ureteral injury was only present 30% of the time. Hence, this is why we defined injuries as cases where a surgical repair was performed.


Abstract

2. 95% confidence intervals should be used with the odds ratios if possible.

This has been added to the abstract (line 180-189)

3. The percentage of cases in which bladder or ureteral injuries occurred should be included.

This has been added to the abstract (line 177-179)

Introduction

4. Line 157 likely "re" operation?

This has been corrected

5. Would be helpful to define the specific rates of injury along with fistula rates from the literature.

See editor comment #1
Methods

6. Is data on outpatient follow-up available? Presumably some patients may have delayed recognition of a fistula that healed with conservative management?

This is a limitation, and has been included in our discussion as our cohort is limited to inpatient or outpatient surgeries (line 887-889)

We do feel however that the limitation of potentially missing fistulas managed as an outpatient is unlikely to greatly impact our results and conclusions. This is because while there are likely some cases where fistulas have been successfully managed non-operatively, the success rate of conservative management alone is reported to be low (<10% of cases) and in our experience never is sufficient (5).


Results

7. Seems unusual that 93% of patients were outpatient procedures yet 37% had an abdominal hysterectomy?

Line 502, most of the hysterectomies (92.5%) were inpatient procedures

8. Were obstetric hysterectomies included?

They were included, although we did not initially specifically identify them in the prior version of our manuscript. For this revision, we identified a total of 2,077 women who underwent an obstetric hysterectomy over the time period. The overall incidence of emergency obstetric hysterectomy in developed countries estimated to be 0.05% (6). Given there are approximately 500,000 births in California per year (7), over our 7 year study period we find a rate of obstetric hysterectomy of 0.05%, entirely consistent with literature. We added this information to our results.

Not surprisingly, the rate of an injury occurring was significantly higher in patients undergoing obstetric hysterectomy as compared to the rest of the cohort (n=145, 7.0% versus 1.8%, p<0.001). This information was added to the manuscript (line 509-511)– we appreciate the suggestion.
9. Might be interesting to breakdown the timing of the delayed repair cases a bit more.

Details of the timing of delayed repair are included in the results section (line 537)

Discussion

10. Overall well written with acknowledgement of limitations

Thank you!

Reviewer #2: Thank you for doing a deep dive into a very dicey topic! Your paper is novel because you separate delayed identification vs immediate identification of lower urinary tract injury. The long follow-up 2005-2011 using this Statewide Database is also important. I think the introduction, methods and discussion are very well written and referenced.

Thank you

RESULTS:
1) Can you please mention what percent of the total 296,130 patients had cystoscopy done at the time of the abdominal, laparoscopic, vaginal and LAVH procedures? Similarly, what percent of the patients with delayed injuries had a cystoscopy at the time of the initial surgery. The paper discusses stent placement but this basic piece of information is missing from the manuscript.

Figure 1 is the money shot, and I think an interesting corollary for discussion is reviewing those patients with delayed identification of injuries, who actually also had intra-operative cystoscopy. Of course the surgeon could have mistakenly missed an injury that was present (e.g. hole in bladder trigone, stitch in bladder, lack of efflux from a ureter) but delayed injuries purportedly occur due to thermal injury and tissue necrosis. I know that we would be asking you to separate details even more than the way you have already laid out in this manuscript, but this one more data point has clinical practice significance.

While we appreciate the comment of the reviewer we are very hesitant to include this information in the manuscript due to serious limitations in the identification of cystoscopy
using procedure codes and the possibility of misinterpretation of such information. Cystoscopy is bundled and not separately identifiable UNLESS there is a diagnosis code listed that identifies a distinct indication for cystoscopy or is performed by another surgeon. Therefore, the cystoscopies we are able to identify were likely performed in cases with a high index of suspicion for injury and potentially where another surgeon was called in to perform the procedure, making these cases inherently more likely to ultimately develop an injury (see in the table below how cases where cystoscopy was performed have higher rates of injury, underlying this bias). Secondly, there is no way to know whether the cystoscopy was performed to check repair of injury or to look for injury, similarly making it difficult to draw conclusions regarding the association between cystoscopy and the risk of genitourinary injury, or its efficacy as a diagnostic tool, as we cannot control for this in the multivariate analysis.

To appropriately respond to all comments we have included a table below for the Editor to review the data. However we request that the Editor take into consideration our concerns regarding including this information in the manuscript. We are happy to discuss further if requested by the Editor and would include a paragraph discussing the issue if requested.

Rates of cystoscopy identified separate from hysterectomy by surgical approach (a) and type of injury (b)

<table>
<thead>
<tr>
<th>Surgical Approach</th>
<th>Cystoscopy identified</th>
<th>Cystoscopy not identified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=18,013</td>
<td>n=278,117</td>
</tr>
<tr>
<td><strong>Timing of injury identification</strong></td>
<td><strong>Immediate</strong></td>
<td><strong>Delayed</strong></td>
</tr>
<tr>
<td>Abdominal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total n=109,188</td>
<td>328 (10.4%)</td>
<td>17 (0.5%)</td>
</tr>
<tr>
<td>Cystoscopy n=3,168 (2.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total n=62,860</td>
<td>235 (3.3%)</td>
<td>38 (0.5%)</td>
</tr>
<tr>
<td>Cystoscopy n=7,103 (11.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total n=77,415</td>
<td>208 (5.5%)</td>
<td>19 (0.5%)</td>
</tr>
<tr>
<td>Cystoscopy n=3,770 (4.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAVH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total n=36,348</td>
<td>145 (4.6%)</td>
<td>16 (0.5%)</td>
</tr>
<tr>
<td>Cystoscopy n=3,174 (8.7%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2) Concomitant prolapse and incontinence surgery at the time of hysterectomy makes your analysis more complicated. Although the numbers are small, what percent of cystotomy injuries were at the time of the anti-incontinence procedures? A small cystotomy at the time of a synthetic sling placement happens frequently (up to 10% if learners involved) but has no real long-term sequelae. But an injury to the trigone at the time of hysterectomy or vaginal mesh placement is a completely different story. Is there any way to tease this out--location matters (dome vs trigone)--because for future fistula formation, location, location, location really matters.

Unfortunately, this cannot be identified from this administrative database. That being said, a small trocar injury to the bladder would not be counted as a bladder injury unless there was a formal surgical repair. Thus, the injuries being reported here are beyond the self-limited small cystotomies.

3) Delayed or unidentified injuries are what lead most to litigation, as you mention. A thermal injury related to endometriosis surgery that results in a uretero-vesicovaginal fistula is much more defensible when a normal cystoscopy was done at the time of the original surgery than a ureterovesical fistula that develops postoperatively and no cystoscopy was performed. Can you break this down more, understanding that cystotomy at the dome or telescope using a lighted scope are other options to intraoperatively evaluate ureteral and bladder integrity.

For the reasons above, we cannot answer this question directly. What can be said however, is cystoscopy is associated with a lower proportion of injuries sustained being of the delayed identification type.

Reviewer #3:

1. Do you have any information on the surgeons who performed these cases or is the identification limited to the hospital? It seems more likely that urinary tract injury would be related to low volume surgeons rather than low volume hospitals. While it is probably true that
lower volume hospitals will have lower volume surgeons, it would be interesting to know the rate of complications related to individual surgeon case volume.

**Unfortunately, we only have granularity to the facility level. We agree that it is a reasonable assumption that lower volume facilities have lower volume surgeons.**

2. Is there any information available on whether a cystoscopy was performed at the time of hysterectomy?

*See above comments to reviewer #2.*

3. How are cases converted from one approach to another handled? For example, a case converted from vaginal or laparoscopic to open? If you code these as open, you may falsely increase the rate of complications with open cases if, for example, the injury occurred during the first part of the case. You could look at your data based on intention to treat. This could help reduce the possibility of making the open approach seem more morbid than it actually would be if not used to salvage difficult vaginal or laparoscopic cases- possibly where a urinary tract injury has already occurred.

*This is a fantastic point. We identified a total of 3,823 cases where there was a conversion from laparoscopic to open.*

The rates of injury in these cases was 4.5%, as compared to 1.9% in cases that were not converted to open (p<0.001). However, even when considering these patients as being in the laparoscopic group (ie intention to treat), the injury rate in the open surgery cohort was still significantly higher (2.0% versus 1.8%, p=0.014).

*This was added to the manuscript (line 580-584)*

4. How do you define "mesh placed"- is this strictly vaginal mesh placed for prolapse or does it include sacrocolpopexy mesh, midurethral slings?

*This strictly refers to mesh placed for pelvic organ prolapse. Unfortunately, we cannot be 100% certain if this mesh was placed vaginally or transabdominally. However it would be reasonable to assume the mesh was placed via the same surgical approach of the hysterectomy.*

5. Since the data is from 2005 to 2011, do you think there might be any difference if the data from more recent years was examined?

*I think the biggest change we would see is less mesh placement (both for slings and pelvic organ prolapse repairs) and potentially greater utilization of cystoscopy – however this is conjecture only.*

6. Black race was protective but Asians were at higher risk for urinary tract injury (table 3). How
can these differences be explained?

This is an interesting point and it has been shown to be the case in other studies. Although the differences could be related to an underlying biologic difference between the two groups, I think that it is much more likely due to confounding factors.

One study found that while 15% of Caucasian women (aged 40-55) had a history of hysterectomy, only 7% of Asian women did (potentially selecting for fewer, more urgent cases) (8). Further, Asian women have been shown to have higher rates of endometriosis (which we found to be associated with the highest risk of injury).

The study referenced above also noted that Black women were the most likely to undergo hysterectomy and the most likely to have a fibroid diagnosis. This might suggest that Black women in particular have less access to non-surgical management options.

These points have been added to the discussion (line 813-842).


STATISTICAL EDITOR COMMENTS:

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

lines 56-63: Should re-organize this section. First, the n(%) for ≥ 1 GU injury should be cited overall and for the immediate vs delayed cohorts. Second, the rates of fistula formation among those subsets should be cited as n(%) for bladder, ureteral and combined, contrasting the immediate vs delayed groups.

This information has been reorganized

Finally, the figures cited on line 59 are not consistent with Fig 1. The rate of bladder fistula formation was 43/1789 (2.3%) vs 4/95 (4.2%) which had p = .28. The rates for ureteral fistulae were 14/2214 (0.6%) vs 10/429 (2.3%), with p < .001. The fistula rates for combined were 6/162 (3.7%) vs 3/12 (25%), with p = .002.

Here I included the combined cases in each group (rate of bladder fistula formation is (43+6)/(1789+162)
Would also be informative to cite rates of GU injury and fistula formation as incidence per 1000 women, with CIs to put findings in context.

This has been included in the discussion section

Also, since the study was observational, with either stent or operative repair for ureteral or combined injuries, should either attempt to adjust for that difference and/or acknowledge that difference in surgical approach for immediate vs delayed cohorts might have affected subsequent rates of fistula formation.

We expanded our results and discussion to include more exploration of surgical approach. This includes surgical approach (ie lap versus open) as well as the method of repair (ie stent versus formal surgical repair).

Tables 1, 2: Suggest separating the p-values into a separate column and more explicitly identifying the referent groups. Also, need to enumerate all missing values, since some of the individual characteristic totals do not equal the sums cited for total or injury columns

Suggested edits made to the tables.
We discuss which groups are not mutually exclusive in the methods section and in the table footnotes.

Table 3: Since this is a multivariate model, should have separate column(with CI) for crude, then adjusted ORs.

This crude OR have been included in Tables 1,2 per the Editor’s request

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor’s specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

***The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.***

- We do not require that initial submissions adhere to the Green Journal publication requirements. Articles for which a revision is requested however, do require that the revised submission adhere to all Green Journal formatting requirements. We strongly recommend that you read the Instructions for Authors to be able to present your revised submission in a format that is likely to allow for a prompt final decision. For instance, the Key Points here are not part of our journal features.

- The objective for the abstract should be a simple "to" statement without background.
- In both the abstract and the paper, please provide absolute numbers as well as which ever effect size you are reporting (if appropriate) + Confidence intervals. P values may be omitted for space concerns. We strongly prefer CI's as they give more information about strength of association than do P values. By absolute values, I mean something like xx (outcome in exposed)/yy(outcome in unexposed) (zz%) (Effect size= ; 95% CI= ). An example might be: Outcome 1 was more common in the exposed than the unexposed 60%/20% (Effect size=3;95% CI 2.6-3.4).

This has been adjusted in the abstract, tables and manuscript

- Please consult the Instructions for Authors regarding the use of abbreviations, and what constitutes an acceptable abbreviation. This is not an acceptable abbreviation. Please spell out all abbreviations on first use. It is reasonable to not use abbreviations for words that are seldom used in the paper. We try to limit “unique” abbreviations so that readers don’t have to frequently refer back to the first notation of the abbreviation to remember its meaning. We realize that this may affect word count but believe it makes it easier in most cases for the reader.

This was corrected

- It is not clear if this 834 is part of the 4800 approximate ureteral and bladder injuries, or are they are 3rd group?

This refers to the total number of fistulas that developed (either after a repair or as a first presentation. The wording was adjusted to clarify this point

- Please note that effect sizes (RR, OR) within the zone of potential bias should be noted as weak. Those effect sizes in the zone of potential interest should be emphasized. (Ref: False alarms and pseudo-epidemics. The limitations of observational epidemiology. Grimes DA, Schulz KF. Ob Gyn 2012;120:920-7). In the discussion section of your paper, please address this as a limitation.

This point is included in the discussion

- you can drop the "often" since you give the % of time they are unrecognized.

This was adjusted

- please delete the colon and the a), b) and c)'s. you can separate the 3 choices by a comma. Please also avoid single sentence paragraphs.

This was corrected
- Please provide information regarding how these databases are validated for accuracy. Since your study is based on clinical coding, is it known how accurately the databases reflect the true CPT and ICD-9 (or 10) codes for what was done?

We discuss in our limitations section of our discussion that OSHPD has a low error tolerance level of less than 2%


- The Journal style doesn’t not use the virgule (/) except in numeric expressions. Please edit here and in all instances.

This change has been made

- see note above re:abbreviation use

- This is called a primacy claim: yours is the first, biggest, etc…In order to assert that, you need to provide the search terms used and the data base (s) searched (PubMed, Google Scholar, etc) to substantiate the claim. Otherwise, it needs to be deleted. It wouldn’t belong in the abstract anyway, so make sure you address this in the manuscript body.

These sections have been edited.

- Since it seems your study confirms prior studies, what makes it distinct? What new findings does it add?

This study is one of the largest of it’s kind and not only completely assess all types of genitourinary injury after hysterectomy but to also assess risk factors for sustaining or failing to recognize such injuries. Further, we also explore the impact of timing on repair, demonstrating the increased risk of fistula if an injury is not repaired immediately and the increased effectiveness of stent placement alone for management of a ureteral injury if it is identified immediately.

- I don't think "less minimally invasive" applies to open hysts. Minimally invasive refers to other means but one would never consider an open case even minimally minimally invasive.

This has been clarified

- Make sense here to perhaps mention which GU tract injuries would likely be missed with universal cysto, such as thermal injuries.
See our responses about cystoscopy above, which does indeed detail some cases where cystoscopy failed to identify an injury (especially delayed fistula formation).

We expanded our discussion here to include this point.

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

This has been reworded

- again, as all of your OR's are > 1 and < 2.00 or. < 1 and > 0.3, please make sure you comment on the zone of potential bias.

This was included in our limitation section

2. 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:
   a. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

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

3. 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.

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

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

This statement has been included in the cover letter

5. 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 has been included

6. Please submit a completed STROBE checklist.

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.

This has been included

7. 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.
8. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.


This was included on the title page

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).

This rules have been adhered to

10. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

Running foot: Urologic Injury Following Hysterectomy

11. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."
Précis: Genitourinary injury occurs in 1.8% of benign hysterectomies. Immediate identification and repair reduces the risk of subsequent genitourinary fistula formation.

12. 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.

The abstract has been carefully reviewed

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.

See Title page

13. 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.

This has been carefully reviewed

14. 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.

The Virgule symbol has been removed

15. Line 306-309: We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

Although we did do an extensive literature review in preparing this manuscript, we have adjusted this phrasing

16. 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.
The Table checklist has been reviewed, and tables carefully edited to comply

17. 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 updated our reference to the most recent committee opinion, copied below


18. When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

Please recheck your arithmetic in Figure 1 to make sure it is correct.

Figure 1 has been carefully reviewed.

19. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acd/accounts/ifauth.htm.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

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submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Apr 25, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief
The authors greatly appreciate the extra time to complete these revisions. Please see attached the revised manuscript, the additional requested appendix tables and our responses.

Kai Dallas, MD
PGY-6
Stanford University, Department of Urology

Dear Dr. Dallas:

You may take until May 6 to return the next version if needed. I will be out of the office from May 1-3.

Thanks,
Randi

Thank you for your email. I have been working diligently on these set of edits to have it ready for your requested April 29th resubmission.

That being said, there were many requested edits and it is not yet ready for re-review. Would it be possible to request an extension on these sets of edits until this Thursday? I want to make sure all concerns are fully addressed adequately.

Thank You,
Kai Dallas MD
PGY-6
Stanford University, Department of Urology

Get Outlook for iOS
Dear Dr. Dallas:

Your revised manuscript is being reviewed by the Editors. Before a final decision can be made, we need you to address the following queries. Please make the requested changes to the latest version of your manuscript that is attached to this email. Please track your changes and leave the ones made by the Editorial Office. Please also note your responses to the author queries in your email message back to me.

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

2. Precis: Please note the Editors’ requested changes to this sentence. Please also edit your Abstract-Conclusion to say something similar.

3. Line 113: This isn’t clear to me. How can 834 (the n for GU fistulas) be 2.8% if the n-2817 for ureteral injuries be only 1%? Is this a typo or am I missing something? I think it should be 0.28%

4. Line 133: Is this what you meant? 80/834?

5. Line 118: Please avoid causal language. What do you mean: “Indwelling stent placement was more successful [for what? Preventing fistula?]”

6. Line 121: What is mesh augmentation? Sorry, I’m an MFM. Do you mean adding some mesh to augment prior mesh placement? If you mean Mesh placement for prolapse could you say that instead and be accurate?

7. Line 124: Please note the Editor’s requested suggestion. Please make this change throughout your submission.

8. Line 151: Not sure that something that occurs around 1% of the time is really rare. Also, to be succinct, could you say: “These injuries are unrecognized at the time of surgery in up to 87% of cases”

9. Line 155: It’s not the incidence that is non trivial but the disease burden, isn’t it?

10. Line 158: Either is a binary choice and you have 3 options here. Please delete “Either”

11. Line 161: Can you please state these as primary and secondary outcomes? You have an aim and then secondary outcome. The terminology should be consistent.

12. Line 165: Throughout your paper, please correct “benign indications” as done here. The hysterectomy isn’t benign or malignant, it’s the nature of the indication.

13. Line 170: The Editors would like you to include the two tables from your revision’s cover letter [Rates of cystoscopy identified separate from hysterectomy by surgical approach (a) and type of injury (b)] as Supplemental Digital Content. Depending on where you insert this in your text, you may need to renumber the current Appendix
files. The Editor would also like you to add a brief paragraph outlining your concerns about ascertainment bias somewhere in your text.

14. Line 251: Here you have 0.3% suggesting that the abstract is incorrect. Since you go to the 2\textsuperscript{nd} decimal for bladder injuries (0.70%) please state 0.28% here.

15. Line 266: Is success measured here as lack of fistula only? What about risks of stenosis, for instance, as a delayed injury? I just want you to be specific about how you define successful management of a ureteral injury, here and elsewhere (including abstract) as needed.

16. Line 272: What is the implication of the limited # (18.7%) with identified ureteral injury? It seems that means that in about 80% stents are being placed perhaps preoperatively to help ID the ureters (for instance in endometriosis patients” or if the surgeon is really worried but just didn’t see an injury. Please comment.

17. Line 282: Is this accurate? Converted to “open” is to jargon-y.

18. Line 310 (related to Query 13): Please add a section here regarding cystoscopy. This should explain the reasons you gave in the response to the reviewers and why you have concerns about the interpretation of the cysto data with a brief summary of the pertinent findings. and then provide the data in the supplemental digital content (the tables you provided).

19. Line 314: This is called a primacy claim: yours is the first, biggest, etc...In order to assert that, you need to provide the search terms used and the database(s) searched (PubMed, Google Scholar, etc) to substantiate the claim, and the years searched. Otherwise, it needs to be deleted. You provided some information in your response to my comments to explain what your paper adds to the extant literature. It would be good to state that here to be clear to the reader what you are adding.

20. Line 326: Please confirm that this is what you meant.

21. Line 328: Instead of endoscopic (as that could mean through a laparoscope and I think you mean stent placement) could you state it clearly?

22. Line 330: This whole paragraph is an argument against publishing your paper—tell the reader in the discussion what you’ve added.

23. Line 351: Please add a citation and reference to the text for this statement. You may need to renumber your current citations and references if you are adding something new here.

24. Line 351-353 (highlighted sentence): I’ve read this sentence several times and still don’t understand what you mean. How does urgency have anything to do with history of hysterectomy? Any way, all of these patients did NOT have a prior hysterectomy. Sorry, I’m just not getting this.

25. Line 355: Which study? What in this study addressed access to non-surgical management options? You provided no data, for instance, of how many AA women had had prior UAE for fibroids who then went on to have fibroids (a measure of access to non-surgical management) or those who had wanted non-surgical management but couldn’t get it.

26. Line 390: Please add some commentary here again about your lack of confidence in the cysto data you provide in SDC.
27. Line 405: How does this temper that concern? Maybe another 500 women had an injury that got treated in Oregon within the first 3 months. You would have missed them, too.

To facilitate the review process, we would appreciate receiving a response by April 29.

Best,
Randi Zung

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Randi Zung (Ms.)
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1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

This has been performed

2. Precis: Please note the Editors’ requested changes to this sentence. Please also edit your Abstract-Conclusion to say something similar.

This has been adjusted

3. Line 113: This isn’t clear to me. How can 834 (the n for GU fistulas) be 2.8% if the n-2817 for ureteral injuries be only 1%? Is this a typo or am I missing something? I think it should be 0.28%

This was a Typo, it should read 0.3%.

4. Line 133: Is this what you meant? 80/834?

Yes, this is correct

5. Line 118: Please avoid causal language. What do you mean: “Indwelling stent placement was more successful [for what? Preventing fistula?] What we meant here was that the patients did not require a second definitive repair (injury healed with stenting alone). This was clarified.

6. Line 121: What is mesh augmentation? Sorry, I’m an MFM. Do you mean adding some mesh to augment prior mesh placement? If you mean Mesh placement for prolapse could you say that instead and be accurate?

This refers to mesh augmented prolapse repair. The wording was adjusted

7. Line 124: Please note the Editor’s requested suggestion. Please make this change throughout your submission.

This was corrected

8. Line 151: Not sure that something that occurs around 1% of the time is really rare. Also, to be succinct, could you say: “These injuries are unrecognized at the time of surgery in up to 87% of cases”

This was corrected

9. Line 155: It’s not the incidence that is non trivial but the disease burden, isn’t it?

This is an excellent point, the wording was adjusted

10. Line 158: Either is a binary choice and you have 3 options here. Please delete “Either”

This correction was made
11. Line 161: Can you please state these as primary and secondary outcomes? You have an aim and then secondary outcome. The terminology should be consistent.  

This was corrected

12. Line 165: Throughout your paper, please correct “benign indications” as done here. The hysterectomy isn’t benign or malignant, it’s the nature of the indication.  

This wording was corrected

13. Line 170: The Editors would like you to include the two tables from your revision’s cover letter [Rates of cystoscopy identified separate from hysterectomy by surgical approach (a) and type of injury (b)] as Supplemental Digital Content. Depending on where you insert this in your text, you may need to renumber the current Appendix files. The Editor would also like you to add a brief paragraph outlining your concerns about ascertainment bias somewhere in your text.  

This has been added to the Appendix and manuscript as requested. We also included the limitations of this data in our discussion

14. Line 251: Here you have 0.3% suggesting that the abstract is incorrect. Since you go to the 2nd decimal for bladder injuries (0.70%) please state 0.28% here.  

This was corrected

15. Line 266: Is success measured here as lack of fistula only? What about risks of stenosis, for instance, as a delayed injury? I just want you to be specific about how you define successful management of a ureteral injury, here and elsewhere (including abstract) as needed.  

This was corrected. We defined in our methods and clarified throughout the paper that we are specifically referring to additional surgeries to repair the ureter after a stent is placed (ie a future reimplant).

16. Line 272: What is the implication of the limited # (18.7%) with identified ureteral injury? It seems that means that in about 80% stents are being placed perhaps preoperatively to help ID the ureters (for instance in endometriosis patients” or if the surgeon is really worried but just didn’t see an injury. Please comment.  

These stent placement referred to here is not referring to the temporary ureteral catheters typically placed pre-operatively to help identify the ureters. We are specifically referring to indwelling stent placement.

As we discussed, diagnosis codes are not as accurate as procedure codes. We performed this sensitivity analysis to show that even when being as a conservative as possible in regards to identifying cases where an injury occurred (ie only including cases where an injury was specifically coded), our findings of high success with immediate stenting remains.

17. Line 282: Is this accurate? Converted to “open” is to jargon-y.
Agree with the changes implemented.

18. Line 310 (related to Query 13): Please add a section here regarding cystoscopy. This should explain the reasons you gave in the response to the reviewers and why you have concerns about the interpretation of the cysto data with a brief summary of the pertinent findings, and then provide the data in the supplemental digital content (the tables you provided).

This was included in the new draft.

19. Line 314: This is called a primacy claim: yours is the first, biggest, etc... In order to assert that, you need to provide the search terms used and the database(s) searched (PubMed, Google Scholar, etc) to substantiate the claim, and the years searched. Otherwise, it needs to be deleted. You provided some information in your response to my comments to explain what your paper adds to the extant literature. It would be good to state that here to be clear to the reader what you are adding.

This was updated.

20. Line 326: Please confirm that this is what you meant.

This was clarified.

21. Line 328: Instead of endoscopic (as that could mean through a laparoscope and I think you mean stent placement) could you state it clearly?

This was adjusted.

22. Line 330: This whole paragraph is an argument against publishing your paper—tell the reader in the discussion what you’ve added.

A major strength of our study is that it corroborates the findings of several smaller studies with its large population based dataset. Several of the studies we reference are limited by small sample sizes or of limited scope. In addition, we identified the risk factors for sustaining an injury or failing to recognize an injury, if one occurred—which is a strength unique to our study. Furthermore, our exploration of the impact a rate of cystoscopy performed at the time of hysterectomy is novel in a population based study.

We have adjusted our phrasing to better highlight these points.

23. Line 351: Please add a citation and reference to the text for this statement. You may need to renumber your current citations and references if you are adding something new here.

This citation is citation 20. I adjusted the paragraph to be less repetitive.

24. Line 351-353 (highlighted sentence): I’ve read this sentence several times and still don’t understand what you mean. How does urgency have anything to do with history of hysterectomy? Any anyway, all of these patients did NOT have a prior hysterectomy. Sorry, I’m just not getting this.
This paragraph was restructured. What we were trying to highlight was the fact that this study (reference 20) highlighted the fact that Black women were more likely to undergo hysterectomy than other races for identical conditions and were less likely to be offered alternative therapies prior. Thus, hysterectomies performed in Black women are less likely to be performed in salvage cases (which are theoretically more technically difficult).

25. Line 355: Which study? What in this study addressed access to non-surgical management options? You provided no data, for instance, of how many AA women had had prior UAE for fibroids who then went on to have fibroids (a measure of access to non-surgical management) or those who had wanted non-surgical management but couldn’t get it.

This study (reference 20) specifically detailed how black women were 1.7 times more likely to undergo hysterectomy (OR, 1.7; 95% CI, 1.5–1.9). Furthermore, the study also highlighted that black women were more likely to undergo hysterectomy that was classified as “inappropriate”.

We have restricted this discussion to phrase these points clearly.

26. Line 390: Please add some commentary here again about your lack of confidence in the cysto data you provide in SDC.

The results and discussion has been expanded to include the cystoscopy data and a discussion of it’s limitations.

27. Line 405: How does this temper that concern? Maybe another 500 women had an injury that got treated in Oregon within the first 3 months. You would have missed them, too.

What we were trying to implying here was that most women probably wouldn’t move to a new State within such a close time period to their surgery. We do acknowledge, however, that certainly some did, and we adjusted the phrasing here.
Thank you for your careful edits. The Figure looks perfect. I am attaching the legend with the corrections you requested.