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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)\*

Personal or nonessential information may be redacted at the editor's discretion.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: <a href="mailto:obgyn@greenjournal.org">obgyn@greenjournal.org</a>.

<sup>\*</sup>The corresponding author has opted to make this information publicly available.

**Date:** Apr 30, 2021

To: "Lauren E Giugale"

**From:** "The Green Journal" em@greenjournal.org

**Subject:** Your Submission ONG-21-639

RE: Manuscript Number ONG-21-639

Outcomes following Total Vaginal Hysterectomy with Uterosacral Ligament Suspension versus Supracervical Hysterectomy with Sacrocervicopexy for Uterovaginal Prolapse

## Dear Dr. Giugale:

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 May 21, 2021, we will assume you wish to withdraw the manuscript from further consideration.

## **REVIEWER COMMENTS:**

Reviewer #1: The authors present a retrospective cohort study comparing prolapse recurrence among patients undergoing laparoscopic supracervical hysterectomy with mesh sacrocervicopexy vs. vaginal hysterectomy with uterosacral suspension. They examined cases at their institution from 2009-2019, n=654. Their primary outcome was composite prolapse recurrence, which included prolapse beyond the hymen or reintervention with surgery or pessary. They found that significantly more patients experienced recurrent prolapse after USLS (15%) than SCH (9%).

Line 104 - Why was a convenience sample used? This seems like a study amenable to determining a power calculation based on available data in the published literature.

Line 129-30 - How likely is it that differences in technique could account for differences in prolapse recurrence (e.g. permanent vs. absorbable suture in USLS)? Are differences in surgeon technique more likely among the vaginal procedures than the laparoscopic ones?

Line 138 - Uteri were placed an a specimen bag for extraction even before 2013?

Line 140 - Why was propensity scoring used to account for confounders? This ended up reducing the sample size substantially—by about 25% from 916 to 680. Why not include the entire group and control for confounders with logistic regression?

Line 152 - Can the authors explain this better: "Notably, there were large amounts of missing data for perioperative complications, as this data was collected as a modification to the initial study protocol and not initially collected for a subset of patients." It sounds like the authors initially did not collect data on periop complications and then modified their methods to obtain these data. If so, why not go back and get it for all subjects? That seems much preferable to simply excluding these subjects. It's not clear what would preclude them from obtaining information on periop complications, since the data were obtained via chart review.

Line 168 - Follow-up time seems relatively short. For the USLS group, the 75% percentile was less than a year. Is there a reason why followup for the USLS group was so much shorter?

Line 183 - The primary driver of recurrent prolapse was anterior prolapse (10.% vs 3%). Is this clinically important, either from a symptom or a surgical perspective?

Line 233 - It seems like an important limitation that there was not sufficient followup in this study to meaningfully evaluate

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apical or posterior prolapse. Differences could either narrow or further separate, with significant deviation in implications.

Line 286 - Again, it's not clear why they needed to match the cohorts on variables such as surgeon, rather than controlling for them. The issue of which surgeon performed which procedures is an important one. Controlling for the skill of the surgeon is always difficult in retrospective studies. In this case, one also has the added challenge that some surgeons likely routinely select one method over the other. Those who primarily do SCH might have better technical skill in general, and thus better outcomes.

Line 287 - It is helpful that the authors did perform another analysis, controlling for surgeon, but it's not clear why this wasn't done in the first place.

Reviewer #2: Title: Outcomes following Total Vaginal Hysterectomy with Uterosacral Ligament Suspension versus Supracervical Hysterectomy with Sacrocervicopexy for Uterovaginal Prolapse

General Comments: In this study the authors seek to compare prolapse recurrence following primary surgical treatment of uterovaginal prolapse by either TVH-USLS or SCH-SC techniques. The study design is a retrospective cohort study using propensity scoring to control for outside variables. The primary outcome assessed was recurrent prolapse beyond the hymen or any retreatment of prolapse with either surgery or pessary. Secondary outcomes included comparisons of complications within 6 weeks of surgery as well as mesh complications, overall reoperation rates—which included surgery for prolapse and for mesh complications, and time to prolapse recurrence. The topic is of interest to the practicing obstetrician gynecologist. Overall the paper is well written. The topic is clinically relevant and interesting. The authors have opened a door for a prospective study to answer the questions remaining due to the retrospective nature of this study.

- 1. The authors should be very clear that the mean follow-up was less than a year in both groups. An indication of the normal routine follow-up for this practice would be helpful. Further emphasis that this represents short term follow-up should be included in the paper.
- 2. I am very interested in the authors' views regarding the disparate rates of concomitant procedures between the groups. According to Table 1, Anterior repair, posterior repair, and perineorrhaphy were each performed in over 50% of the initial TVH-USLS patients, but fewer than 10% of the SCH-SC patients. This is not addressed in the analysis.
- 3. Did surgeons select a vaginal approach if there appeared to be a more compartmental prolapse requiring repair? As there are different causes of a cystocele—midline defects, lateral defects, and apical descent "traction" cystoceles—were patients selected for a vaginal approach if they had more evidence of non-apical causes of prolapse?
- 4. Does the concomitant repair of cystocele/rectocele improve outcome (if reoperation rates were similar between groups, one could argue otherwise)?
- 5. Finally, are surgeons who are more likely to do concomitant repairs also more likely to treat recurrence earlier?
- 6. I find it interesting that the follow up intervals are relatively short given this was a study which was able to review data over a ten-year period. Were the patients lost to follow up? Were the patients, as a group, primarily referrals to the academic center who then returned to their primary care-givers?
- 7. The conclusions of the authors mirror the conclusions of the meta-analysis by Siddiqui, Grimes, Casiano, et al cited in lines 71-73. The conclusion of no significant difference between overall reoperation rates, although an important observation, is different than the primary outcome goal, which was a comparison of recurrent prolapse by technique (lines 90-91; 108-110). The data presented support the stated objectives of identifying differences in rates of recurrent prolapse and of retreatment for prolapse—these are clinically significant findings. I would consider emphasizing them in the conclusion.
- 8. I appreciate the attention paid to racial disparity and the attempt to consider why this might be the case.
- 9. Line 125: "Reoperation for midurethral sling complications or subsequent surgery for urinary incontinence were not included in the number for overall reoperation." I think that it is important to include the numbers of women who underwent MUS surgery or surgery for incontinence following their repair. It is plausible that with sacrocolpopexy, more women would have to undergo anti-incontinence surgery because of the tension placed on the anterior vaginal wall. Please include these data and whether or not it affects the number of women who needed follow-up operations.
- 10. Line 152: "Notably, there were large amounts of missing data for perioperative complications, as this data was collected as a modification to the initial study protocol and not initially collected for a subset of patients." Fewer than half of the women have these data; please either review the rest of the charts (preferred) or delete these data.
- 11. Line 151: In assessing perioperative complications, the authors note there were "large amounts of missing data" (line 151) as these data were "not initially collected for a subset of patients" (line 153). It leaves me curious as to how large the missing subset was compared to the sample size and how this might have affected the analysis—for example, there are no data regarding ureteral injury rates for the SCH-SC group (Table 2; line 380). If there were significant differences in ureteral injury rates, this may affect the final analysis. If the amount of "missing data" is substantial, the comparisons of complications may have little validity. I would like to see more information in this regard.
- 12. The authors emphasize that the reoperation rates for the two procedures are similar but do not remark that the reoperation rates are low.
- 13. Line 274: "Despite matching on relevant clinical variables, it is likely that there are factors for which we are not accounting in the present study." Should read "accounting for..."
- 14. Line 288: "Recognizing that this could bias our results, we ran a separate model controlling for surgeon and it did not change the results of our primary outcome or interpretation of the models." This is a result and the data should be included in the results section and then commented on in the discussion section. Please revise.
- 15. A flow diagram would be helpful to understand which patient were included and which were not.

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Reviewer #3: 1. How does this report differ from your previous publication? (Your reference 10)

- 2. With only 14 black patients, can you draw any conclusions?
- 3. How many patients in each group developed urinary incontinence?
- 4. How do average surgical times and costs differ between the two approaches?
- 5. Do the robotic versus non-robotic approaches show any differences in outcome, surgical times and costs?
- 6. Comment on the much higher incidence of posterior repairs in the vaginal procedures.

### STATISTICAL EDITOR COMMENTS:

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

Lines 148-150: There were 10 variables included as adjustors (those listed plus 4 subcategories of pre-op POPQ measurements, but with age, BMI, advanced prolapse having been matched by propensity, so in reality, there were 7 variables used as adjustors). This number is unfavorable vs the counts of adverse outcomes (prolapse recurrence). Thus it is very likely that the model is over fitted. Should simply cite the K-M analysis with caveats re: the unmatched variables, or do another analysis with further matching. Also, were the recurrence of prolapse events evaluated as to whether they occurred consistent with a proportional hazards model?

Table 1: Should move the outcome variables section to a separate Table. Should enumerate all missing data.

Table 2: Although stated in the footnote, should indicate more clearly which variables were missing. It appears that for the SCH SC group, most of the n=426 did not have data for the various complications, so how can one compare rates of any perioperative complication? The only category that had a plurality of non-missing data was "ileus or small bowel obstruction". For all others,  $\sim 2/3$  of data were missing, so this is not representative and cannot be generalized to comparison of outcomes.

Table 3: Since CIs are provided, the column of p-values is redundant and should be omitted. Should indicate in footnote whether the HRs are crude vs adjusted and if adjusted, then list the variables included in the final model.

Fig 1: Although the methodology is known as survival analysis, the outcome in this case is proportion with prolapse recurrence. Should re-label the y-axis and Title. Since there were no data for TVH USLS at the 1000, 1500 and 2000 day increments and ) for the SCH ASC at 2000 days, should truncate the x-axis at 1000 days and increase the number of increments. Should then include the number remaining at risk in each cohort at the new increment levels.

# **EDITOR COMMENTS:**

- 1. The comments of reviewer #1 notwithstanding, we actually encourage propensity matching over multivariable analysis. As per our statistical reviewer, if you choose to revise, we ask that you match on a greater number of variables.
- 2. Given the high proportion of missing complication data, we ask that you remove the complication analyses.
- 3. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
- A. OPT-IN: Yes, please publish my point-by-point response letter.
- B. OPT-OUT: No, please do not publish my point-by-point response letter.
- 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.

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5. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a

formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

- 6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.
- 7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.
- 8. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
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- \* 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).
- \* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."
- 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 limit for Original Research articles is 300 words. Please provide a word count.

- 10. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.
- 11. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

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

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

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. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, 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 at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top).

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

- \* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
- \* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

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 May 21, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2019 IMPACT FACTOR: 5.524

2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

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May 18th, 2021 Dwight J. Rouse, MD, MSPH Editor-in-Chief Obstetrics & Gynecology

Dear Dr. Rouse,

Please find enclosed our revised manuscript entitled "Outcomes following Total Vaginal Hysterectomy with Uterosacral Ligament Suspension versus Supracervical Hysterectomy with Sacrocervicopexy for Uterovaginal Prolapse," which we have submitted exclusively to *Obstetrics & Gynecology* to be considered for publication as an original article.

We sincerely appreciate the comments and critiques from the reviewers, statistical editor, and editor. We have addressed each review and have provided a point-by-point response as outlined on the following pages. We have also submitted our revised manuscript with tracked changes on Editorial Manager.

The lead author, Lauren Giugale, 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 have been explained. We have reviewed the Instructions for Authors.

We thank you again for your consideration of our work.

For correspondence concerning this manuscript, please using the following contact information:

Lauren E. Giugale, MD Urogynecology and Pelvic Floor Reconstructive Surgery Department of Obstetrics, Gynecology & Reproductive Sciences Magee-Womens Hospital of UPMC

Sincerely,

Lauren Giugale, MD

Laur Jugar

### **REVIEWER COMMENTS:**

Reviewer #1: The authors present a retrospective cohort study comparing prolapse recurrence among patients undergoing laparoscopic supracervical hysterectomy with mesh sacrocervicopexy vs. vaginal hysterectomy with uterosacral suspension. They examined cases at their institution from 2009-2019, n=654. Their primary outcome was composite prolapse recurrence, which included prolapse beyond the hymen or reintervention with surgery or pessary. They found that significantly more patients experienced recurrent prolapse after USLS (15%) than SCH (9%).

Line 104 - Why was a convenience sample used? This seems like a study amenable to determining a power calculation based on available data in the published literature.

- We utilized a convenience sample of all cases available for chart review to obtain the largest possible sample size, given the retrospective design and that some cases would be excluded after propensity score matching. We aimed to have the largest possible sample size to detect a significant difference if one truly exists. We have added this explanation to our methods section, Line 104-106: "We utilized a convenience sample to maintain the largest possible sample size given the retrospective nature and need to exclude cases during propensity score matching."
  Line 129-30 How likely is it that differences in technique could account for differences in prolapse recurrence (e.g. permanent vs. absorbable suture in USLS)? Are differences in surgeon technique more likely among the vaginal procedures than the laparoscopic ones?
  - Thank you for this excellent point. You are correct that because of the retrospective design, we could not standardize procedures and thus variations in surgical procedure which may impact the results. However, we think this impact should be minimal based upon prior literature demonstrating similar outcomes between permanent and absorbable suture for USLS. Based upon our data presented in Table 1, variation in surgical technique may be more common with vaginal procedures. Additionally, we could not control for concomitant repairs because of collinearity with the procedure type itself. However, we do not think this would necessarily impact our results based upon previously published data that did not demonstrate an impact of concomitant procedures on anatomic outcomes after vaginal uterosacral ligament suspensions. Finally, we feel that this increases the generalizability of our results given the small nuances to all surgeon's approach to POP surgery. We have added additional description to our limitations section not further address this point, Lines 346-351 "We also do not think variations in surgical procedure are likely to have impacted our outcomes. Prior literature has demonstrated similar outcomes between permanent and absorbable suture and similar outcomes regardless of whether concomitant anterior and posterior repairs were performed at the time of vaginal USLS. Additionally, small variations in surgeon approach lends to the generalizability of our results." We have also added the following references:
    - 8. Nager CW, Grimes CL, Nolen TL, et al. Concomitant Anterior Repair, Preoperative Prolapse Severity, and Anatomic Prolapse Outcomes After Vaginal Apical Procedures. Female Pelvic Med Reconstr Surg. 2019;25(1):22-28. 10.1097/SPV.0000000000000526
    - 13. Bradley MS, Bickhaus JA, Amundsen CL, et al. Vaginal Uterosacral Ligament Suspension: A Retrospective Cohort of Absorbable and Permanent Suture Groups. Female Pelvic Med Reconstr Surg. 2018;24(3):207-212. 10.1097/SPV.0000000000000451

- 14. Kowalski JT, Genadry R, Ten Eyck P, Bradley CS. A randomized controlled trial of permanent vs absorbable suture for uterosacral ligament suspension. Int Urogynecol J. 2021;32(4):785-790. 10.1007/s00192-020-04244-1
- 15. Sutkin G, Zyczynski HM, Sridhar A, et al. Association between adjuvant posterior repair and success of native tissue apical suspension. Am J Obstet Gynecol. 2020;222(2):161 e161-161 e168. 10.1016/j.ajog.2019.08.024

Line 138 - Uteri were placed an a specimen bag for extraction even before 2013?

Thank you. You are correct that some procedures were performed prior to the FDA safety ban
on power morcellation. The following sentence has been edited, Lines 137-141 "The uterus was
either removed via laparoscopic morcellation if the procedure was performed prior to the Food
and Drug Administration ban on power morcellation or placed in a specimen bag and removed
through the umbilicus prior to the conclusion of the procedure if performed after the 2014
safety ban."

Line 140 - Why was propensity scoring used to account for confounders? This ended up reducing the sample size substantially—by about 25% from 916 to 680. Why not include the entire group and control for confounders with logistic regression?

- Thank you for this question. We have edited Line 143-144, which now reads "We utilized propensity scoring to account for factors that could influence or confound either the procedure choice (confounding by indication) or prolapse recurrence."
- Propensity scoring attempts to account for confounding by indication. We also discuss our
  rationale in Lines 310-315, which have been edited and now read: "By using propensity scoring a
  priori, we were able to balance our retrospective cohorts on variables that may impact surgery
  choice or prolapse recurrence. Propensity score matching addresses confounding by indication
  better than a traditional logistic regression model. While it is impossible to eliminate all bias in a
  retrospective cohort, this methodology allowed us to minimize confounding by indication and
  produce less biased estimates of treatment effects."
- Lastly, the Obstetrics and Gynecology Instructions for Authors document has a section regarding
  propensity score matching in which they encourage authors to utilize propensity score matching
  if the authors believe that propensity score matching will allow adjustments to create cohorts
  that are more statistically equivalent at baseline, believing this approach would strengthen their
  submission. Thus, we felt that propensity score matching was the most appropriate statistical
  method to utilize for this study. Please let us know if you would like an additional description of
  this thought process in the manuscript.

Line 152 - Can the authors explain this better: "Notably, there were large amounts of missing data for perioperative complications, as this data was collected as a modification to the initial study protocol and not initially collected for a subset of patients." It sounds like the authors initially did not collect data on periop complications and then modified their methods to obtain these data. If so, why not go back and get it for all subjects? That seems much preferable to simply excluding these subjects. It's not clear what would preclude them from obtaining information on periop complications, since the data were obtained via chart review.

• Thank you for this point. You are correct that the large amount of missing postoperative complication data is a large limitation of the current study. You are also correct that the complication data for this study was collected as part of a modification after initial data collection had begun as described in Lines 154-156. As per our IRB protocol, the dataset has now been deidentified and we unfortunately do not have a way in which to go back and collect this information. Additional concerns regarding the perioperative complication data are addressed below in subsequent reviews and revisions.

Line 168 - Follow-up time seems relatively short. For the USLS group, the 75% percentile was less than a year. Is there a reason why followup for the USLS group was so much shorter?

• Thank you for this point. We have edited Lines 333-339, which now read "Another likely reason for the differential loss to follow up in the TVH USLS group is that patients undergoing native tissue repair often return to their primary gynecologist for annual examinations after the initial 6 week and 3-month postoperative visits, whereas patients with SCH SC are instructed to follow up in our office for annual mesh surveillance. A prospective study design in which long-term follow up is standardized would better account for this discrepancy between prolapse repair groups."

Line 183 - The primary driver of recurrent prolapse was anterior prolapse (10.% vs 3%). Is this clinically important, either from a symptom or a surgical perspective?

• Thank you for this interesting question. We have addressed this question in Lines 244-253 which now read "This information is important as it improves our understanding of how these procedures differ in terms of postoperative anatomic support. Yet, how to use this information clinically to improve anatomic and subjective outcomes after TVH USLS is less clear, given that prior research has not necessarily shown a benefit of anterior repair at the time of TVH USLS.... Longer follow-up and prospective study design will be important in describing and comparing the anatomic durability of laparoscopic SCH SC."

Line 233 - It seems like an important limitation that there was not sufficient followup in this study to meaningfully evaluate apical or posterior prolapse. Differences could either narrow or further separate, with significant deviation in implications.

 Thank you for this comment. We agree with your comment and have addressed this limitation in Lines 328-329, "Prospective studies should be performed to confirm our findings and to assess for differences in apical and posterior recurrence that may develop over longer follow up intervals."

Line 286 - Again, it's not clear why they needed to match the cohorts on variables such as surgeon, rather than controlling for them. The issue of which surgeon performed which procedures is an important one. Controlling for the skill of the surgeon is always difficult in retrospective studies. In this case, one also has the added challenge that some surgeons likely routinely select one method over the other. Those who primarily do SCH might have better technical skill in general, and thus better outcomes.

 Thank you for addressing this point. We address this important concept in Lines 315-318 "During study design, we chose not to match on the surgeon variable because it did not result in good balance between cohorts. Recognizing that this could bias our results, we ran a separate model controlling for surgeon and it did not change the results of our primary outcome or interpretation of the models" which addresses the question posed by this reviewer. We recognize the reviewer's excellent point, which was our rationale for running a separate model controlling for surgeon to ensure that the surgeon variable was not impacting our results as described above. Please also refer to the newly edited lines 310-315 which add additional explanation for propensity scoring as described above in a preceding review.

Line 287 - It is helpful that the authors did perform another analysis, controlling for surgeon, but it's not clear why this wasn't done in the first place.

• Thank you for this question. We did try to perform propensity score matching for surgeons a priori, however controlling for surgeon did not result in good balance between cohorts as described in the prior response and in Lines 315-318.

Reviewer #2: Title: Outcomes following Total Vaginal Hysterectomy with Uterosacral Ligament Suspension versus Supracervical Hysterectomy with Sacrocervicopexy for Uterovaginal Prolapse

General Comments: In this study the authors seek to compare prolapse recurrence following primary surgical treatment of uterovaginal prolapse by either TVH-USLS or SCH-SC techniques. The study design is a retrospective cohort study using propensity scoring to control for outside variables. The primary outcome assessed was recurrent prolapse beyond the hymen or any retreatment of prolapse with either surgery or pessary. Secondary outcomes included comparisons of complications within 6 weeks of surgery as well as mesh complications, overall reoperation rates—which included surgery for prolapse and for mesh complications, and time to prolapse recurrence. The topic is of interest to the practicing obstetrician gynecologist. Overall the paper is well written. The topic is clinically relevant and interesting. The authors have opened a door for a prospective study to answer the questions remaining due to the retrospective nature of this study.

- Thank you for these comments and for your review.
- 1. The authors should be very clear that the mean follow-up was less than a year in both groups. An indication of the normal routine follow-up for this practice would be helpful. Further emphasis that this represents short term follow-up should be included in the paper.
  - Thank you for this comment. We have emphasized these points. Line 175-177 now reads
    "Median follow-up was less than 1 year for both prolapse repair groups. Median follow up
    after SCH SC was 230.0 days (IQR 92.8-505.8, range 18-1912 days) compared to 125.5 days
    after TVH USLS (IQR 78.3-353.5, range 16-1449 days) (p<0.0001)." Line 46 of the abstract has
    also been edited accordingly.</li>
  - To better describe practice patterns at our institution, Lines 331-337 now read "Another likely reason for the differential loss to follow up in the TVH USLS group is that patients undergoing native tissue repair often return to their primary gynecologist for annual examinations after the initial 6 week and 3-month postoperative visits, whereas patients with SCH SC are instructed to follow up in our office for annual mesh surveillance. A prospective study design in which long-term follow up is standardized would better account for this discrepancy between prolapse repair groups."
  - The short-term follow up of our study population has been emphasized throughout in Lines 56, 213, 361.

- 2. I am very interested in the authors' views regarding the disparate rates of concomitant procedures between the groups. According to Table 1, Anterior repair, posterior repair, and perineorrhaphy were each performed in over 50% of the initial TVH-USLS patients, but fewer than 10% of the SCH-SC patients. This is not addressed in the analysis.
  - Thank you for this comment. Reviewer #1 also had a similar question which we have addressed above as well. Because of the retrospective design, we could not standardize procedures and thus variations in surgical procedure which may impact the results. Additionally, we could not control for concomitant repairs because of collinearity with the procedure type itself. However, we do not think this would necessarily impact our results based upon previously published data that do not consistently demonstrate an impact of concomitant procedures on anatomic outcomes after vaginal uterosacral ligament suspensions. Lines 344-349 have been revised to reflect this explanation: "We also do not think variations in surgical procedure are likely to have impacted our outcomes. Prior literature has demonstrated similar outcomes between permanent and absorbable suture and similar outcomes regardless of whether concomitant anterior and posterior repairs were performed at the time of vaginal USLS. Additionally, small variations in surgeon approach lends to the generalizability of our results."
  - We have also added the following citations/references:
    - 8. Nager CW, Grimes CL, Nolen TL, et al. Concomitant Anterior Repair, Preoperative Prolapse Severity, and Anatomic Prolapse Outcomes After Vaginal Apical Procedures. Female Pelvic Med Reconstr Surg. 2019;25(1):22-28. 10.1097/SPV.000000000000526
    - 15. Sutkin G, Zyczynski HM, Sridhar A, et al. Association between adjuvant posterior repair and success of native tissue apical suspension. Am J Obstet Gynecol. 2020;222(2):161 e161-161 e168. 10.1016/j.ajog.2019.08.024
- 3. Did surgeons select a vaginal approach if there appeared to be a more compartmental prolapse requiring repair? As there are different causes of a cystocele—midline defects, lateral defects, and apical descent "traction" cystoceles—were patients selected for a vaginal approach if they had more evidence of non-apical causes of prolapse?
  - Thank you for this question. Because of the retrospective study design, we cannot comment on why a specific surgical procedure was chosen. Recognizing this important limitation and the possibility of confounding by indication, we utilized propensity score matching for our statistical methods. Lines 308-313 describe this rationale: "By using propensity scoring a priori, we were able to balance our retrospective cohorts on variables that may impact surgery choice or prolapse recurrence. Propensity score matching addresses confounding by indication better than a traditional logistic regression model. While it is impossible to eliminate all bias in a retrospective cohort, this methodology allowed us to minimize confounding by indication and produce less biased estimates of treatment effects."
- 4. Does the concomitant repair of cystocele/rectocele improve outcome (if reoperation rates were similar between groups, one could argue otherwise)?

- Thank you for this interesting question. Unfortunately, this is a question we cannot answer with the current study design. This is certainly an interesting clinical question for future work which we do discuss in Lines 243-248 "Specifically for the anterior compartment, SCH SC had a significantly lower proportion of prolapse beyond the hymen compared to TVH USLS. This information is important as it improves our understanding of how these procedures differ in terms of postoperative anatomic support. Yet, how to use this information clinically to improve anatomic and subjective outcomes after TVH USLS is less clear, given that prior research has not necessarily shown a benefit of anterior repair at the time of TVH USLS." and Lines 328-329 "Prospective studies should be performed to confirm our findings and to assess for differences in apical and posterior recurrence that may develop over longer follow up intervals."
- 5. Finally, are surgeons who are more likely to do concomitant repairs also more likely to treat recurrence earlier?
  - Thank you for this interesting question. We unfortunately cannot answer or comment on this question based upon the data available. This would be an interesting future research question.
- 6. I find it interesting that the follow up intervals are relatively short given this was a study which was able to review data over a ten-year period. Were the patients lost to follow up? Were the patients, as a group, primarily referrals to the academic center who then returned to their primary care-givers?
  - Thank you for this question and recognizing an important limitation of our study. While we cannot know the specific reasons for lost to follow up because of the retrospective design, we have commented on possible reasons and address the reviewer's question in Lines 329-337 "Additionally, we cannot comment on reasons for loss to follow up, one of which could be seeking care with another provider if prolapse recurrence had developed. Another likely reason for the differential loss to follow up in the TVH USLS group is that patients undergoing native tissue repair often return to their primary gynecologist for annual examinations after the initial 6 week and 3-month postoperative visits, whereas patients with SCH SC are instructed to follow up in our office for annual mesh surveillance. A prospective study design in which long-term follow up is standardized would better account for this discrepancy between prolapse repair groups."
- 7. The conclusions of the authors mirror the conclusions of the meta-analysis by Siddiqui, Grimes, Casiano, et al cited in lines 71-73. The conclusion of no significant difference between overall reoperation rates, although an important observation, is different than the primary outcome goal, which was a comparison of recurrent prolapse by technique (lines 90-91; 108-110). The data presented support the stated objectives of identifying differences in rates of recurrent prolapse and of retreatment for prolapse—these are clinically significant findings. I would consider emphasizing them in the conclusion.
  - Thank you for these recommendations. We have added an additional paragraph to the
    Discussion section, line 255-263 "While retreatment for prolapse was significantly more
    common among women who underwent TVH USLS, we did not demonstrate a significant
    difference in rates of overall reoperation between TVH USLS and SCH SC, which were low in both
    groups. These similar reoperation rates are in concordance with prior meta-analysis data.3

Given the discrepancy between significant differences in anatomic durability and retreatment without significant differences in overall reoperation rate, the incorporation of subjective patient-centered outcome measures will be imperative to assess the clinical significance of our findings. Evaluating and understanding what matters more to patients, retreatment for prolapse versus overall chance of reoperation, will be important knowledge to inform surgical counseling and procedure selection."

- 8. I appreciate the attention paid to racial disparity and the attempt to consider why this might be the case.
  - Thank you. We are eager to evaluate this finding further.
- 9. Line 125: "Reoperation for midurethral sling complications or subsequent surgery for urinary incontinence were not included in the number for overall reoperation." I think that it is important to include the numbers of women who underwent MUS surgery or surgery for incontinence following their repair. It is plausible that with sacrocolpopexy, more women would have to undergo anti-incontinence surgery because of the tension placed on the anterior vaginal wall. Please include these data and whether or not it affects the number of women who needed follow-up operations.
  - We agree with the reviewer that this is a very interesting and important clinical question.
     Unfortunately, we do not have this data in the current study and we are unable to go back and collect the data because of the de-identified nature of the data set. This is an interesting question for future study designs.
- 10. Line 152: "Notably, there were large amounts of missing data for perioperative complications, as this data was collected as a modification to the initial study protocol and not initially collected for a subset of patients." Fewer than half of the women have these data; please either review the rest of the charts (preferred) or delete these data.
  - Thank you for bringing up this important limitation and your concern. We agree that because of the large numbers of missing data, comparative outcomes on the postoperative complications should not be performed. Thus, we have removed comparative assessment for the postoperative complications and solely provide the raw numbers. We do think that inclusion of the available raw data, while limited, is important and we have made it clear to the reader that the complication data is not complete.
  - Table 3 has been edited to reflect the above changes.
  - Additionally, we have removed mention of comparison of perioperative complication data throughout the manuscript as comparative analyses for these variables is not appropriate given the large amount of missing data. These changes are tracked throughout the manuscript.
- 11. Line 151: In assessing perioperative complications, the authors note there were "large amounts of missing data" (line 151) as these data were "not initially collected for a subset of patients" (line 153). It leaves me curious as to how large the missing subset was compared to the sample size and how this might have affected the analysis—for example, there are no data regarding ureteral injury rates for the

SCH-SC group (Table 2; line 380). If there were significant differences in ureteral injury rates, this may affect the final analysis. If the amount of "missing data" is substantial, the comparisons of complications may have little validity. I would like to see more information in this regard.

- Thank you for this important point. We agree with your comments and suggestions and have addressed them in the preceding review/revision. Please see the above comment.
- 12. The authors emphasize that the reoperation rates for the two procedures are similar but do not remark that the reoperation rates are low.
  - Thank you for this point. We have emphasized that the reoperation rates were low throughout the Discussion section and these changes are tracked.
- 13. Line 274: "Despite matching on relevant clinical variables, it is likely that there are factors for which we are not accounting in the present study." Should read "accounting for..."
  - Thank you. This typographical error has been corrected.
- 14. Line 288: "Recognizing that this could bias our results, we ran a separate model controlling for surgeon and it did not change the results of our primary outcome or interpretation of the models." This is a result and the data should be included in the results section and then commented on in the discussion section. Please revise.
  - Thank you. We agree this should be mentioned in the Results section and we have added to Lines 206-209 "Of note, we did not match a priori for surgeon because it did not result in good balance (SMD values >0.10) between the cohorts after propensity score matching. We did run a separate model controlling for surgeon and it did not change the results of our primary outcome or interpretation of the models as presented above (data not shown)."
- 15. A flow diagram would be helpful to understand which patient were included and which were not.
  - Thank you for this comment. The statistical editor's comments asked that we include an additional Table. Thus, our manuscript currently has four Tables and one Figure. We think that adding an additional Figure would be too cumbersome for the manuscript. Thus, we have added an additional description to the results section to help the reader understand how we arrived at the final cohort of patients. Lines 165-170 now read "Prior to propensity scoring, a total of 916 patients met inclusion criteria over the study period consisting of 236 (25.8%) TVH USLS and 680 (74.2%) SCH SC procedures. After propensity score matching on the variables of age, BMI, diabetes, current tobacco use, and advanced prolapse as described above, 262 (28.6%) patients were excluded. The final propensity score matched cohort for analysis consisted of 654 patients. There were 228 (34.9%) TVH USLS and 426 (65.1%) SCH SC procedures in the final cohort."

### Reviewer #3:

- 1. How does this report differ from your previous publication? (Your reference 10)
  - Thank you for this question. The reference cited was a comparison stratified by prolapse stage to assess how the procedures comparatively perform among different stages of prolapse. Additionally, this cited study included sacrocolpopexy for vaginal vault prolapse

(women with prior hysterectomy) and thus represents a different patient population than that assessed in the present study.

- 2. With only 14 black patients, can you draw any conclusions?
- We agree with your question that we cannot draw any conclusions based upon the low number of black women in our study. We acknowledge this in Lines 287-289 "Black women were statistically less likely to undergo sacrocervicopexy than white women, although this should be interpreted considering an overall low proportion of black women in our study population." We refrain from drawing any conclusions. Rather, we think this finding should prompt future research as noted in Lines 295-296 "We intend to utilize this data to prompt further research into health disparities within our community and specifically within our urogynecology patient population."
- 3. How many patients in each group developed urinary incontinence?
  - This is a very interesting and important clinical question. Unfortunately, we do not have this data in the current study and we are unable to go back and collect the data because of the deidentified nature of the data set.
- 4. How do average surgical times and costs differ between the two approaches?
  - These are both interesting questions. Unfortunately, we do not have this data in the current study. A cost-effective analysis would be a very interesting comparison in future research additionally inform preoperative decision making from a utilization and cost standpoint.
- 5. Do the robotic versus non-robotic approaches show any differences in outcome, surgical times and costs?
  - Thank you for this question. We did not perform any comparisons between robotic and non-robotic approaches for the sacrocervicopexies in this study as this was not one of our primary or secondary outcomes. Additionally, performing this analysis would exclude all of the TVH USLS in our cohort. Thus, this clinical question would likely be better addressed in a separate study with a different primary outcome focused on the specific comparison between robotic and laparoscopic approaches to sacrocervicopexy. We unfortunately do not have any cost data and future cost analyses would be interesting as noted above.
- 6. Comment on the much higher incidence of posterior repairs in the vaginal procedures.
  - Thank you for this comment. Reviewers #1 and #2 also had similar questions. The TVH USLS did have a larger proportion of concomitant prolapse repairs than the SCH SC group. Because of the retrospective design, we could not standardize procedures and thus variations in surgical procedure which may impact the results. Additionally, we could not control for concomitant repairs because of collinearity with the procedure type itself. However, we do not think this would necessarily impact our results based upon previously published data that did not demonstrate an impact of concomitant procedures on anatomic outcomes after vaginal uterosacral ligament suspensions. We have added additional description to our limitations section not further address this point, Lines 344-349 "We also do not think variations in surgical procedure are likely to have impacted our outcomes. Prior literature has demonstrated similar outcomes between permanent and absorbable suture and similar outcomes regardless of

whether concomitant anterior and posterior repairs were performed at the time of vaginal USLS. Additionally, small variations in surgeon approach lends to the generalizability of our results."

- We have also added the following references:
  - 8. Nager CW, Grimes CL, Nolen TL, et al. Concomitant Anterior Repair, Preoperative Prolapse Severity, and Anatomic Prolapse Outcomes After Vaginal Apical Procedures. Female Pelvic Med Reconstr Surg. 2019;25(1):22-28. 10.1097/SPV.0000000000000526
  - 15. Sutkin G, Zyczynski HM, Sridhar A, et al. Association between adjuvant posterior repair and success of native tissue apical suspension. Am J Obstet Gynecol. 2020;222(2):161 e161-161 e168. 10.1016/j.ajog.2019.08.024

#### STATISTICAL EDITOR COMMENTS:

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

Lines 148-150: There were 10 variables included as adjustors (those listed plus 4 subcategories of preop POPQ measurements, but with age, BMI, advanced prolapse having been matched by propensity, so in reality, there were 7 variables used as adjustors). This number is unfavorable vs the counts of adverse outcomes (prolapse recurrence). Thus it is very likely that the model is over fitted. Should simply cite the K-M analysis with caveats re: the unmatched variables, or do another analysis with further matching. Also, were the recurrence of prolapse events evaluated as to whether they occurred consistent with a proportional hazards model?

- Thank you for this comment and question. We think this question has arisen from a misunderstanding of our stage of prolapse POPQ variable. There were not 4 subcategories of POPQ. Rather, POPQ was a dichotomized variable for advanced prolapse (defined as ≥Stage III prolapse as described in the methods section). Thus, there are actually only 6 variables in the final adjusted multivariable cox regression model. In total, 71 patients experienced the primary outcome of composite prolapse recurrence. Thus, the number of variables for which we adjusted is appropriate for the number of occurrences of our primary outcome and our model is not overfit.
- We performed matching on variables clinically thought to affect the outcome of the analysis. There
  are not additional variables on which we would like to match. Additionally, further matching would
  reduce our sample size. Based on this assessment, we did not make any changes and do not think
  any additional matching or analysis is necessary. Please let us know if further clarification is needed.

Table 1: Should move the outcome variables section to a separate Table. Should enumerate all missing data.

• Thank you for these suggestions. The outcome variables have been moved to a separate Table, which is now Table 2. Missing data has been described in the footnotes for each Table.

Table 2: Although stated in the footnote, should indicate more clearly which variables were missing. It appears that for the SCH SC group, most of the n = 426 did not have data for the various complications,

so how can one compare rates of any perioperative complication? The only category that had a plurality of non-missing data was "ileus or small bowel obstruction". For all others,  $\sim 2/3$  of data were missing, so this is not representative and cannot be generalized to comparison of outcomes.

- Thank you for this comment, as noted above, we agree that because of the large numbers of
  missing data, comparative outcomes on the postoperative complications should not be
  performed. Thus, we have removed comparative assessment for the postoperative complications
  and solely provide the raw numbers. We do think that inclusion of the available raw data, while
  limited, is important and we have made it clear to the reader that the complication data is not
  complete.
- Table 3 (previously Table 2) has been edited to reflect the above changes.
- Additionally, we have removed mention of comparison of perioperative complication data throughout the manuscript as comparative analyses for these variables is not appropriate given the large amount of missing data. These changes are tracked throughout the manuscript.

Table 3: Since CIs are provided, the column of p-values is redundant and should be omitted. Should indicate in footnote whether the HRs are crude vs adjusted and if adjusted, then list the variables included in the final model.

• Thank you for this suggestion and comment. The p-values have been omitted as suggested. This table represents adjusted data, and this has been clarified in the table and in the footnotes as suggested. These requested changes have been made to Table 4 (previously Table 3).

Fig 1: Although the methodology is known as survival analysis, the outcome in this case is proportion with prolapse recurrence. Should re-label the y-axis and Title. Since there were no data for TVH USLS at the 1000, 1500 and 2000 day increments and ) for the SCH ASC at 2000 days, should truncate the x-axis at 1000 days and increase the number of increments. Should then include the number remaining at risk in each cohort at the new increment levels.

• Thank you for this suggestion. The recommended changes have been made and the revised Figure has been uploaded to Editorial Manager. The Figure Legend has also been revised as suggested in Lines 470-471.

### **EDITOR COMMENTS:**

- 1. The comments of reviewer #1 notwithstanding, we actually encourage propensity matching over multivariable analysis. As per our statistical reviewer, if you choose to revise, we ask that you match on a greater number of variables.
- Thank you for this comment. As described above, we think the statistical editor's question arose from a misunderstanding of our stage of prolapse POPQ variable. There were not 4 subcategories of POPQ. Rather, POPQ was a dichotomized variable for advanced prolapse (defined as ≥Stage III prolapse as described in the methods section). Thus, there are actually only 6 variables in the final adjusted multivariable cox regression model. In total, 71 patients experienced the primary outcome of composite prolapse recurrence. Thus, the number of variables for which we adjusted is appropriate for the number of occurrences of our primary outcome and our model is not overfit.

- We performed matching on variables clinically thought to affect the outcome of the analysis. There are not additional variables on which we would like to match. Additionally, further matching would reduce our sample size. Based on this assessment, we did not make any changes and do not think any additional matching or analysis is necessary. Please let us know if further clarification is needed.
- 2. Given the high proportion of missing complication data, we ask that you remove the complication analyses.
  - We agree that we should not perform comparative analyses for the complication data given the
    large amount of missing data. We have removed the comparative analyses for postoperative
    complication data as suggested. We do think the reader will be interested in the limited
    complication data available, thus we have still reported on the raw numbers without
    comparisons. Please let us know if you would like us to remove all of the complication data
    completely.
- 3. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
- A. OPT-IN: Yes, please publish my point-by-point response letter.
  - We agree to having our point-by-point response letter published.
  - B. OPT-OUT: No, please do not publish my point-by-point response letter.
- 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 our cover letter.
- 5. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

## Completed

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at <a href="https://urldefense.com/v3/">https://urldefense.com/v3/</a> <a href="https://urldefense.com/v3/">https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions</a> ;!!NHLzug!eW06vu7tt3-</a> <a href="https://urldefense.com/v3/">WPIOTyxO8UkNDky0x1snWFatj2HTUyr6XJHbTvKrHOzkLfbs\_6FFIfw\$</a> and the gynecology data definitions at <a href="https://urldefense.com/v3/">https://urldefense.com/v3/</a> <a href="https://urldefense.com/v3/">https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions">https://urldefense.com/v3/</a> <a href="https://urldefense.com/v3/">https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions">https://urldefense.com/v3/</a> <a href="https://urldefense.com/v3/">https://urldefense.com/v3/</a> <a href="https://urldefense.com/v3/">htt

- 7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.
  - We are in compliance with these guidelines. The current word count is 5,074 words.
- 8. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
- \* All financial support of the study must be acknowledged.
- \* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- \* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- \* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
- \* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

## Completed

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 limit for Original Research articles is 300 words. Please provide a word count.

• We have reviewed our abstract. The word count is 291 words.

10. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

# Completed

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

Revisions completed as per the statistical editor guidelines.

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

NA

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

# Completed

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:

https://urldefense.com/v3/ http://edmgr.ovid.com/ong/accounts/table\_checklist.pdf\_;!!NHLzug!eW06vu7tt3-WPloTyxO8UkNDky0x1snWFatj2HTUyr6XJHbTvKrHOzkLfbvrg08\_1w\$.

- Completed
- 13. Please review examples of our current reference style at <a href="https://urldefense.com/v3/">http://ong.editorialmanager.com</a>;!!NHLzug!eW06vu7tt3-</a>
  <a href="https://urldefense.com/v3/">WPIoTyxO8UkNDky0x1snWFatj2HTUyr6XJHbTvKrHOzkLfbs0GxuCHw\$</a> (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.
- Reviewed and reference style edited as appropriate.

In addition, 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 at the Clinical Guidance page at <a href="https://urldefense.com/v3/">https://www.acog.org/clinical</a>;!!NHLzug!eW06vu7tt3-WPloTyxO8UkNDky0x1snWFatj2HTUyr6XJHbTvKrHOzkLfbsfIHVP9A\$ (click on "Clinical Guidance" at the top).

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