

# OBSTETRICS & GYNECOLOGY



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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)\*

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[obgyn@greenjournal.org](mailto:obgyn@greenjournal.org).

**Date:** May 23, 2019  
**To:** "Lauren E. Giugale" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-19-669

RE: Manuscript Number ONG-19-669

Outcomes of A Staged Midurethral Sling Strategy for Stress Incontinence and Pelvic Organ 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 Jun 13, 2019, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1: Well written study. The analysis is thorough and addresses questions commonly asked by FPMRS surgeons regarding whether or not to place concomitant slings at the time of prolapse repair. The authors have done their due diligence in addressing potential areas of bias and Type II error within their discussion.

Reviewer #2: In this retrospective single site study, authors sought to evaluate the proportion of women who experienced resolution of stress urinary incontinence (SUI) in the cohort of women that had surgery for pelvic organ prolapse (POP) without anti-incontinence surgery. They reported resolution of SUI in 37% of patients and concluded that a staged approach to treating women with POP and SUI may lead to surgery avoidance in up to two-thirds of patients.

1. Abstract; authors may wish to add to methods section (lines 27-32) how symptom resolution (primary objective) was measured. Even though authors did not identify factors associated with staged MUS (lines 41-42), concluding, "...staged approach may result in two-thirds fewer MUS and that this information should be incorporated in pre-operative shared decision making" is rather too strong a statement in light of their results (lines 45-46).

2. Introduction; lines 50-53; decision to perform accompanying MUS at the time of POP surgery surely should also reflect patient reported severity of symptoms including any past history of SUI treatment failures?. Lines 67-69; what specific gaps in knowledge do authors' study set to address? Afterall, there are similarly sized studies and some including a randomized trial??

3. Methods; Isn't the real question to be asked is -who needs concomitant MUS surgery at the time of evaluation for POP and SUI? How can this question be answered by excluding patients who had concomitant MUS? By comparing the cohort who had MUS with those without, readers may better understand patient and or physician related factors that drive the decision to perform concomitant MUS surgery. As designed, authors cannot overcome selection bias, namely, there maybe inherent differences in patients that favor symptom resolution in patients not offered MUS.

a. Why the time-range 2009-2015? Were there any changes in practice patterns and personnel over his time period?

b. Since post-operative symptom resolution (primary outcome) was not systematically ascertained (with use of UDI questionnaire and or UDS), how can readers be assured of the integrity of the reported results (from under-reporting and observer bias)? - lines 97-101

4. Statistics; lines 102-106: how many variables were fitted in your regression analyses? Given the small numbers of staged MUS patients (n=34), it is concerning that your analyses is likely unstable. You do not also appear adequately

powered to answer some of the secondary analyses performed. Reliance on univariate analysis on some conclusions is a big study weakness.

5. Results; Small numbers (n=93,) 98% Caucasian population severely limit generalizability. That 7 surgeons performed 93 procedures introduces considerable variability in patient selection criteria (that is not shown) and surgical techniques. Application to most practices is further limited.

a. The average BMI of 28 in this cohort is rather low compared to that seen in many practices. The threshold for obesity -defined as class 1 set the bar rather low; it will be far more practical to understand distribution and the impact of higher classes of obesity (II, III) on the outcomes, however, numbers of obese women are rather small (n=31). Further, understanding the distribution of obesity in this cohort compared to those who had concomitant MUS at initial surgery would have been useful.

b. How many patients were lost to follow up? (lines 121-122) One can infer those patients missing data were lost to follow up? The range of follow up period is quite wide; what proportion of patients had 3 months evaluation vs. 12 months? Loss of data in an already small sample size study is problematic. The overall relatively short follow up period (median time 8.3months) is also weakness.

c. Lines 149-150, 156-157, 162-165 are as a result of lack of adequate power/sample size and are not supported by the data.

6. Discussion; lines 177-179; we simply do not know what factors drove patients decision making or surgeons' factors that led to omitting MUS surgery initially nor do we know what led to those with persistent symptoms undertaking additional MUS surgery. To conclude..." a staged approach to treatment may result in substantial nearly two-thirds reduction in placement of MUS" (lines 177-179) when patients may not have had surgery because "symptoms may have been minimal, finance barriers, surgeons' influence, possibility of care elsewhere" (lines 265-270) is unsupported by your data.

Reviewer #3:

1. This study is a retrospective observational cohort study looking at women who undergo staged MUS after Minimally invasive Sacrocolpopexy versus USLS vaginal or laparoscopic to identify proportion of women who experience resolution of SUI. Objective was well defined

2. Methods: Please define subjective SUI in line 82 with use of preoperative UDI-6

3. Did the authors exclude patients that missing data for subjective and objective data not available-please report this in the methods

4. Please comment on how patients are counseled (endorsed line 65-67) preoperatively to undergo staged procedure-Did patients choose or did the surgeons choose who went on to undergo stage procedure versus concomitant. I think this could be a selection bias for patients who choose staged MUS and should be included in limitations of study in discussion.

5. How many charts were reviewed to report percentage that did undergo concomitant MUS versus staged population

6. Methods: how was the follow up reported SUI noted in documentation-was there a standard post op note that include yes or no to sui, if there was no documentation at all about symptoms of sui post op how where these patients recorded in study (for example were they excluded or included as no sui post op)

7. Table 1: race has only white and black: would be interesting if possible to look at the data as ethnicity to have more generalizable understanding of progression of disease within Caucasian, Hispanic, Asian, African American, or Native American

8. Line 131 for Figure 2 I would suggest change title to be chosen treatments or therapies for women who reported persistent SUI after prolapse surgery

9. Results: line 127-128 why did these patients not undergo post operative testing. Were these women who decided not to undergo therapy or surgical interventions?

10. For population practice would be interesting to look at women who underwent MUS post operatively did they all get post op testing such as cystometry/UDS or did the preoperative testing show SUI prior to placing a MUS.

11. Discussion on lines 188-191 could indicate a selection bias to this data based on if this population at the beginning who chose not to undergo MUS concomitant may more likely not want to undergo MUS post op despite still being symptomatic. This is less of a bothersome report and more could be related to other fears or personality/perceived bias.

This relates to comment 4 and can be added as limitation in discussion

12. Overall authors did a great job discussing limitations to study

13. Overall conclusion: I believe that conclusion to help with surgical counseling is appropriate based on this data and that stating further research to address this question is still needed.

#### STATISTICAL EDITOR'S COMMENTS:

1. lines 33-39: Since the total cohort had  $n = 93$ , there is no basis to cite proportions with precision to nearest 0.1%, should round to whole percentages. The same stipulation re: citing percentages should be adhered to throughout the manuscript.

2. Table 1: Many of the comparisons involve small counts and there is little power to generalize the NS findings

3. Fig 1, 2: Not within these figures, but elsewhere in manuscript, the estimates of percentages should include CIs, to put them in context.

#### EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

- 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.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

3. Was this paper presented at ICS 2018 in Philadelphia? If so, please disclose the name, dates, and location of the meeting on your title page.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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

6. 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).

7. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

8. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

9. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

10. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: [http://edmgr.ovid.com/ong/accounts/table\\_checklist.pdf](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

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

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

If you submit a revision, we will assume that it has been developed in consultation with your co-authors 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 Jun 13, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

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

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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.

June 12, 2019

Nancy C. Chescheir, MD  
Editor-in-Chief  
*Obstetrics & Gynecology*

Dear Dr. Chescheir,

Thank you very much for your consideration of our manuscript entitled "Outcomes of A Staged Midurethral Sling Strategy for Stress Incontinence and Pelvic Organ Prolapse." We truly appreciate the edits and comments from both you and the reviewers. The reviewers' comments as well as our specific responses to each comment are listed on the following pages. We have also enclosed our revised manuscript with tracked changes.

We are excited to submit these revisions to you, and we hope that you will consider our revised manuscript for publication. Thank you again for your feedback of our work.

For correspondence concerning this manuscript, please using the following contact information:  
Lauren E. Giugale, MD

[REDACTED]

[REDACTED]

*Lauren Giugale*  
[REDACTED]

## REVIEWER COMMENTS:

Reviewer #1: Well written study. The analysis is thorough and addresses questions commonly asked by FPMRS surgeons regarding whether or not to place concomitant slings at the time of prolapse repair. The authors have done their due diligence in addressing potential areas of bias and Type II error within their discussion.

- Thank you.

Reviewer #2: In this retrospective single site study, authors sought to evaluate the proportion of women who experienced resolution of stress urinary incontinence (SUI) in the cohort of women that had surgery for pelvic organ prolapse (POP) without anti-incontinence surgery. They reported resolution of SUI in 37% of patients and concluded that a staged approach to treating women with POP and SUI may lead to surgery avoidance in up to two-thirds of patients.

1. Abstract; authors may wish to add to methods section (lines 27-32) how symptom resolution (primary objective) was measured. Even though authors did not identify factors associated with staged MUS (lines 41-42), concluding, ..."staged approach may result in two-thirds fewer MUS and that this information should be incorporated in pre-operative shared decision making" is rather too strong a statement in light of their results (lines 45-46).

- The definition of symptom resolution was added to lines 32-33. The definition of Subjective SUI was also better defined in lines 100-101.
- Thank you for the second comment. We agree that we do not want to make too strong of a conclusion. We do think it is important to highlight that a large proportion of women who would normally be offered a MUS at the time of prolapse surgery ultimately did not have a sling placed. We have edited lines 40-51 to better deliver this message, which we agree is more consistent with our results. We have also edited the Précis (lines 23-25) to ensure our message is consistent.

2. Introduction; lines 50-53; decision to perform accompanying MUS at the time of POP surgery surely should also reflect patient reported severity of symptoms including any past history of SUI treatment failures?. Lines 67-69; what specific gaps in knowledge do authors' study set to address? Afterall, there are similarly sized studies and some including a randomized trial??

- We agree that patients' symptoms should be considered when deciding whether to perform a concomitant MUS. We have edited lines 69-71, which now reflect this change.
- Thank you for this question and identifying a potential source of confusion. The specific knowledge gap is the outcome of preoperative SUI symptoms after minimally invasive sacrocolpopexies and uterosacral ligament suspensions without a concomitant incontinence procedure. Prior RCTs have addressed the question of prophylactic MUS in women without preoperative SUI, which is a different patient population than in the current study (discussed in lines 55-64). Only limited research has addressed the resolution of preoperative SUI symptoms after transvaginal prolapse repairs and transvaginal mesh-based repairs (discussed in lines 73-76). Thus, more data is needed to describe the outcome of preoperative SUI symptoms after apical prolapse repair without concomitant incontinence procedure, particularly after minimally invasive sacrocolpopexy. To make our clinical question and knowledge gap clearer to the reader, we have rearranged and edited the introduction, lines 53-90.

3. Methods; Isn't the real question to be asked is -who needs concomitant MUS surgery at the time of evaluation for POP and SUI? How can this question be answered by excluding patients who had concomitant MUS? By comparing the cohort who had MUS with those without, readers may better understand patient and or physician related factors that drive the decision to perform concomitant MUS surgery. As designed, authors cannot overcome selection bias, namely, there may be inherent differences in patients that favor symptom resolution in patients not offered MUS.

- Thank you for bringing up this excellent point. Yes, the question of who needs a concomitant MUS surgery is relevant. However, in designing this study, our clinical question was different. Our goal was to determine who has resolution of preoperative SUI and does not ultimately undergo a MUS. We elected this clinical question because it addresses the issue of concomitant MUS with a “less is more” approach. Rather than determine who needs a concomitant MUS, we argue that assessing the course of SUI symptoms after surgery should be understood first. There has been a trend toward placement of concomitant MUS placement, and thus our goal was to offer a different viewpoint regarding SUI symptoms at the time of pelvic organ prolapse repair. Additionally, because of our practice patterns, we are in the position to answer this question, given that we offer a staged MUS approach.
- We are unfortunately not in the position to compare this current study population to a cohort of women who underwent a concomitant MUS, as this would be a different study and we did not collect information on this other cohort of patients. We considered this approach during study design. However, given the observational nature of our study, this approach would introduce confounding by indication and also selection bias, since the decision to perform a concomitant MUS surgery would be inherently linked to their preoperative symptoms. Because we offer a staged MUS approach so frequently, those women who received concomitant MUS would likely have had severe symptoms prompting the concomitant sling placement. However, your point is well taken, and this would be an interesting study to consider in the future either in a randomized trial or in a population less subject to selection bias. These points have been added to the limitations section, lines 315-319.

a. Why the time-range 2009-2015? Were there any changes in practice patterns and personnel over his time period?

- This time range reflects the start of an electronic surgical calendar, which facilitated identification of procedures of interest and chart review. The initial IRB for this study began in 2016, and thus gave us access to chart review through 2015. There were no major changes in practice patterns or personnel over this time period. To clarify our methods, lines 96-97 have been edited.

b. Since post-operative symptom resolution (primary outcome) was not systematically ascertained (with use of UDI questionnaire and or UDS), how can readers be assured of the integrity of the reported results (from under-reporting and observer bias)? - lines 97-101

- Thank you for this very important point. You are correct that both under-reporting and observer bias are both potential problems for which we cannot control. We have added a section to the limitations section to address this issue, lines 307-308.



4. Statistics; lines 102-106: how many variables were fitted in your regression analyses? Given the small numbers of staged MUS patients (n=34), it is concerning that your analyses is likely unstable. You do not also appear adequately powered to answer some of the secondary analyses performed. Reliance on univariate analysis on some conclusions is a big study weakness.

- In the first multivariable logistic regression model assessing for resolution of SUI (n=24), there were only 2 variables in the model: Preoperative UDI 6 and obesity. These variables have now been listed more clearly in [lines 186-187](#). Given that only 2 variables were included in this model, we are not concerned that we have over-fit this model
- In the second multivariable logistic regression model assessing placement of staged MUS, there were 4 variables in the model (preoperative UDI-6 stress symptom bother, preoperative vaginal estrogen use, procedure type, and concomitant hysterectomy). These are listed in [lines 196-198](#). Thus, the reviewer's point about the potential for unstable results is well taken, as the model may be overfit by one variable. However, we discuss in detail throughout the manuscript that this was an exploratory statistical analysis and is likely impacted by missing data ([lines 204-210 and lines 259-266](#)) and results should be interpreted with caution. We agree that no strong conclusions can be drawn from this analysis. However, it does demonstrate that procedure type may impact whether a staged MUS will be needed in the future, and this may be an important topic of further research as we try to determine who should and should not have a concomitant MUS.
- We agree that our small sample size and lack of power is a major limitation of this study, particularly for our comparative secondary outcomes. We address this in [lines 319-325](#). However, our primary outcome (the proportion of women who had subjective resolution of SUI after minimally invasive sacrocolpopexy or uterosacral ligament suspension without a concomitant incontinence procedure) and main conclusions are descriptive. Therefore, because our primary outcome is a descriptive outcome, it should not be impacted by lack of power (although we agree that analyzing a larger sample size would be ideal).

5. Results; Small numbers (n=93,) 98% Caucasian population severely limit generalizability. That 7 surgeons performed 93 procedures introduces considerable variability in patient selection criteria (that is not shown) and surgical techniques. Application to most practices is further limited.

- We agree with your concerns regarding sample size and a predominately white population. These are both addressed in the limitations section, [lines 319-325](#).
- We also agree with your concern regarding surgeon variation in both surgical decision making and surgical technique. However, while on one hand this may be a limitation, this may also increase the generalizability of our findings. We have commented on both of these issues as well in [lines 300-303](#).

a. The average BMI of 28 in this cohort is rather low compared to that seen in many practices. The threshold for obesity -defined as class 1 set the bar rather low; it will be far more practical to understand distribution and the impact of higher classes of obesity (II, III) on the outcomes, however, numbers of obese women are rather small (n=31). Further, understanding the distribution of obesity in this cohort compared to those who had concomitant MUS at initial surgery would have been useful.

- We agree that it would be important to understand how more severe obesity impacts our findings, particularly because obesity was associated with a decreased odds of resolution of SUI.

Unfortunately, given our small sample size, we are unable to analyze our data in this way. However, your point is well taken and we have edited lines 253-256.

b. How many patients were lost to follow up? (lines 121-122) One can infer those patients missing data were lost to follow up? The range of follow up period is quite wide; what proportion of patients had 3 months evaluation vs. 12 months? Loss of data in an already small sample size study is problematic. The overall relatively short follow up period (median time 8.3months) is also weakness.

- Every patient had at least one follow-up visit after surgery. We do not provide a concrete number for lost to follow-up because we did not have a follow-up criterion for inclusion. Rather, we provide a follow-up range as well as reporting the median follow-up. The range of follow up is wide, however this is a real life scenario and a consequence of our retrospective study design. We have added follow-up to our limitations section and discuss that longer follow-up would strengthen our study in lines 322-325.
- Missing data was either the result of patients not providing information in the preoperative assessment (in the case of missing preoperative UDI-6 data) or lack of documentation by the provider in the medical record. Similar to above, this is a limitation of our retrospective study design, which we address in the limitations section. Please also see our responses to Reviewer #3, Points #3 and #6 for more information on missing data and how we have clarified for the reader.
- Regarding your last question, 72 patients (77%) had at least 3 months of follow up and 41 patients (44%) had at least 1 year of follow up. To better describe the follow-up of our cohort to the audience, this information has been added into the results section, lines 159-160.

c. Lines 149-150, 156-157, 162-165 are as a result of lack of adequate power/sample size and are not supported by the data.

- We recognize that sample size and lack of power are significant limitations of this study (please also see our description for item #4 above). This is addressed in the limitations section in lines 319-325.

6. Discussion; lines 177-179; we simply do not know what factors drove patients decision making or surgeons' factors that led to omitting MUS surgery initially nor do we know what led to those with persistent symptoms undertaking additional MUS surgery. To conclude..." a staged approach to treatment may result in substantial nearly two-thirds reduction in placement of MUS" (lines 177-179) when patients may not have had surgery because "symptoms may have been minimal, finance barriers, surgeons' influence, possibility of care elsewhere" (lines 265-270) is unsupported by your data.

- Our primary outcome data is descriptive and demonstrates that among women who would often be offered a concomitant sling, 30% experience resolution of preoperative SUI. Additionally, two-thirds of those women ultimately did not undergo a midurethral sling. This suggests that a staged approach may result in fewer placements of MUS. We agree that we cannot comment on why a MUS was not performed and we have addressed this in our limitations section, lines 308-315. However, we do think that our findings support our conclusion that, for likely a variety of reasons, a staged approach may lead to fewer MUS procedures. Further research is needed to assess why patients are not undergoing MUS procedures and whether a staged approach is truly beneficial. According to your suggestions, we have re-worded our conclusion to be more in line with our data, lines 326-336.

Reviewer #3:

1. This study is a retrospective observational cohort study looking at women who undergo staged MUS after Minimally invasive Sacrocolpopexy versus USLS vaginal or laparoscopic to identify proportion of women who experience resolution of SUI. Objective was well defined.

- Thank you.

2. Methods: Please define subjective SUI in line 82 with use of preoperative UDI-6

- Because not all patients completed a preoperative UDI-6, we actually did not use preoperative UDI-6 data either to define subjective SUI or as an inclusion criteria. Subjective SUI was defined as patient reported symptoms during preoperative consultation, which is described in lines 100-101 of the revised manuscript. Ideally, data would have been collected in a prospective manner (addressed in lines 304-308 in the limitation sections) and all patients would have had preoperative UDI-6 data.

3. Did the authors exclude patients that missing data for subjective and objective data not available-please report this in the methods

- Missing data was less than <5% for all but two variables, and thus did not require further investigation. If missing data was >5% for a variable that was thought to be impacting the results of the multivariable logistic regression, sensitivity analyses were performed and are described in the results section. We have added this information to the methods section, lines 132-136. In the footnotes of Table 1 (lines 403-404), we identify the variables with >5% missing data (preoperative UDI-6 stress bother and Postoperative Ba). Of note, only the preoperative UDI-6 required sensitivity analysis because it was included in the final multivariable logistic regression model. The results of these additional analyses are provided in the results section (lines 204-210) and addressed in the discussion section (lines 259-266).

4. Please comment on how patients are counseled (endorsed line 65-67) preoperatively to undergo staged procedure- Did patients choose or did the surgeons choose who went on to undergo stage procedure versus concomitant. I think this could be a selection bias for patients who choose staged MUS and should be included in limitations of study in discussion.

- Thank you for this excellent point. In our practice, patients with preoperative SUI symptoms are counseled regarding the option of concomitant midurethral sling versus the option of waiting to assess SUI symptoms after prolapse repair. While patients with preoperative SUI are presented with the options of either a staged approach to the treatment of SUI or a concomitant midurethral sling, we frequently endorse a staged approach. Patients are specifically counseled that their SUI symptoms may resolve, persist, or worsen after prolapse repair and that, in the event of bothersome postoperative SUI symptoms, subsequent treatment including a second procedure may be indicated. After counseling, the decision of whether to proceed with a concomitant versus a staged sling is made between the patient and the physician. As is

commonly the case, each surgeons' counseling differs slightly as there is no template by which we counsel. To describe our counseling to the audience, we have added in the above description to the Methods section, lines 113-120.

- You are correct that patient counseling could lead to selection bias and we have addressed this in the limitations section, lines 308-311. Please also see related comment #11 below.

5. How many charts were reviewed to report percentage that did undergo concomitant MUS versus staged population

- Thank you for this question. There were 1007 procedures identified using the surgical calendar over the study period: 816 (81%) minimally invasive sacrocolpopexies and 190 (19%) uterosacral ligament suspensions. Of those, 93 women (9%) met inclusion criteria. One-hundred twenty-eight women (13%) were excluded because they had a concomitant MUS, 776 women (77%) either had no SUI symptoms or SUI was not objectively confirmed, and 10 women (1%) identified using the calendar did not actually have a sacrocolpopexy or uterosacral ligament suspension on chart review. We have added the above numbers to the results section, lines 140-149.

6. Methods: how was the follow up reported SUI noted in documentation-was there a standard post op note that include yes or no to sui, if there was no documentation at all about symptoms of sui post op how were these patients recorded in study (for example were they excluded or included as no sui post op)

- We do have a standard postoperative note template that includes a section for the presence and type of urinary incontinence. Thus, all patients had documentation of whether or not they had subjective SUI symptoms in the postoperative period. This has been added to the methods section, lines 109-112.

7. Table 1: race has only white and black: would be interesting if possible to look at the data as ethnicity to have more generalizable understanding of progression of disease within Caucasian, Hispanic, Asian, African American, or Native American

- Unfortunately, our patient population is quite homogenous and thus there were no other racial categories other than white and black in our cohort. We agree that our data would be more generalizable if more diverse, however this is a limitation of our population which is addressed in the limitations section, lines 319-320.

8. Line 131 for Figure 2 I would suggest change title to be chosen treatments or therapies for women who reported persistent SUI after prolapse surgery.

- Thank you for this excellent suggestion. This change has been made and Figure 2 is now titled "Therapies for Women with Persistent SUI after Pelvic Organ Prolapse Repair" (line 410).

9. Results: line 127-128 why did these patients not undergo post operative testing. Were these women who decided not to undergo therapy or surgical interventions?

- Because of the nature of retrospective chart review, we do not know why postoperative testing was not performed. Possible reasons include lack of reported bother by the patient or surgeon bias, which are similar to the possible reasons some women did not undergo a staged MUS. We discuss this limitation of our retrospective study design in [lines 304-307](#)
- Regarding your second point, no, these were not necessarily the women who did not have treatment. Of the 28 women who did not have postoperative objective SUI testing, 14 (50%) underwent treatment for SUI postoperatively. Seven (50%) of these women had a MUS and 7 underwent PFPT. Given that all of the women in our cohort had objective SUI preoperatively, this is likely the reason that no additional testing was performed in this group of women. This information has been added to the results section in [lines 165-167](#).

10. For population practice would be interesting to look at women who underwent MUS post operatively did they all get post op testing such as cystometry/UDS or did the preoperative testing show SUI prior to placing a MUS.

- Thank you for this comment. We agree that it would be interesting to look at women who underwent a MUS postoperatively to see if they underwent postoperative SUI testing prior to sling placement. Unfortunately, we do not have this exact information at this time. This is an interesting idea and we will consider this for future studies.

11. Discussion on lines 188-191 could indicate a selection bias to this data based on if this population at the beginning who chose not to undergo MUS concomitant may more likely not want to undergo MUS post op despite still being symptomatic. This is less of a bothersome report and more could be related to other fears or personality/perceived bias. This relates to comment 4 and can be added as limitation in discussion

- Thank you for this point. We agree that both patient and provider attitudes/beliefs are likely present which we cannot account for and certainly could contribute an element of selection bias. We have edited the limitations section accordingly, [lines 308-311](#).

12. Overall authors did a great job discussing limitations to study

- Thank you. We recognize that there are significant limitations to this study and our goal is to be transparent in explaining these limitations to the reader.

13. Overall conclusion: I believe that conclusion to help with surgical counseling is appropriate based on this data and that stating further research to address this question is still needed.

- Thank you again for your comments and suggestions. We greatly appreciate your time and consideration of our work.

#### STATISTICAL EDITOR'S COMMENTS:

1. lines 33-39: Since the total cohort had  $n = 93$ , there is no basis to cite proportions with precision to nearest 0.1%, should round to whole percentages. The same stipulation re: citing percentages should be adhered to throughout the manuscript.

- Thank you for this suggestion. We have made these changes throughout the manuscript and in Table 1, as well. Please let us know if we misunderstood this request and you would like the decimal places added back into Table 1, as we would be happy to do this.

2. Table 1: Many of the comparisons involve small counts and there is little power to generalize the NS findings

- Thank you for this point. You are correct that our sample size is small and we are underpowered to detect significant differences for our secondary outcomes. This is a significant limitation of our study and we have addressed this in the limitations section, [lines 319-325](#).

3. Fig 1, 2: Not within these figures, but elsewhere in manuscript, the estimates of percentages should include CIs, to put them in context.

- Thank you for this feedback. The estimates of percentages and CIs for Figure 1 are 30% (95% CI 21%-40%) and 70% (95% CI 61%-79%). The estimates of percentages and CIs for Figure 2 are 28% (95% CI 17-39%), 17% (95% CI 8-26%), 52% (95% CI 40-64%), and 3% (95% CI 0-7.2%). We attempted to include these in the text of the manuscript. However, the numbers displayed in Figure 2 are not actually presented in the manuscript text, which was done intentionally to avoid repetition and redundancy. Thus, we have no good place to report the CIs for Figure 2, as it was specifically requested in the review not to put the CIs into the Figures themselves. Additionally, including the CIs for these percentage estimates but not for the many other proportions reported throughout the manuscript seemed inconsistent. Thus, we elected not to report the CIs for these Figures within the manuscript text. However, we have opted-in to having these revisions published, thus this information will be available to the public through this review. If it is felt strongly that the CIs for Figure 1 and 2 be reported, please let us know and we will determine an appropriate place to report them. Please advise if further clarification or edits are needed.

#### EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

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

- We appreciate this effort at increased transparency and are happy for you to publish our responses.

**B. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.**

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are

ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

- Please remove the prior PDFs from EM as indicated.

3. Was this paper presented at ICS 2018 in Philadelphia? If so, please disclose the name, dates, and location of the meeting on your title page.

- Yes, we apologize for omitting this on the cover page. This research was also presented as a poster presentation at ICS. Because ICS is an international society, we were permitted to present at both AUGS and ICS. We have added this information to the title page.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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

- Our manuscript adheres to these guidelines. The page number (excluding references) is 20 and the final manuscript word count after revisions is 4949 (which includes all pages except the references).

6. 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).

7. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

- We have reviewed the abstract and there are no inconsistencies between the abstract and the manuscript.

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.

- The word count for our abstract is 299 words.

8. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

9. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

10. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: [http://edmgr.ovid.com/ong/accounts/table\\_checklist.pdf](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

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