NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

Questions about these materials may be directed to the Obstetrics & Gynecology editorial office: obgyn@greenjournal.org.
Dear Dr. Sung:

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 referees 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).

***Due to the COVID-19 pandemic, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by Apr 25, 2020, we will assume you wish to withdraw the manuscript from further consideration.***

REVIEWER COMMENTS:

Reviewer #1: The purpose of this manuscript was to "was to identify demographic and clinical variables associated with undesired surgical outcomes at 12 months in women with MUI undergoing MUS." This was a planned, secondary analysis of data previously collected in a randomized trial.

1. The subjects completed a number of validated questionnaires at baseline, 3, 6 and 12 months. Who administered the questionnaires? How were the questionnaires administered; paper, online, combination or other? Was the data put into a database? What was done to ensure accuracy of data recording and transfer to the database? What was done if missing data?

2. Would the authors expand their discussion to include estrogen use, or non-use and failure for patients with MUI undergoing MUS?

3. Could the authors also discuss adverse events like mesh erosion (like they did in manuscript in supplemental materials provided, Table 4) and how they relate to the undesired surgical outcomes?

Reviewer #2: A very well designed and clinically impactful study. The only suggestion that I have is to reconsider the objective stated in the abstract in line 147. It is more clearly defined in the body of the text. This statement suggests that the mid-urethral sling is being used to treat MUI instead of being used to treat the SUI component of MUI. If the authors intend to consider MUS as a treatment for both urge and stress symptoms, this should be stated more clearly. Lastly, considering including that this is an "off label indication" as the MUS is intended as a sub-urethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. Overall, excellent study.

Reviewer #3: The authors present a planned secondary analysis of a randomized trial (ESTEEM) assessing MUS + PFMT vs MUS alone for patients with mixed incontinence (MUI). With this planned secondary analysis, the authors examined two
cohorts (success, and failure) at 12 months postoperatively to identify preoperative characteristics associated with treatment failure following MUS in patients with MUI. They conclude that prior OAB medication use, DO on baseline UDS, low VLPP, and BMI are risk factors for MUI treatment failure with MUS and women with more severe urgency as baseline may benefit from perioperative PFMT.

The authors focus on an important topic as the ability to predict which patients are at high risk of failure is of utmost importance in order to accurately counsel patients regarding expected outcomes of surgery and to assess who will most benefit from a given procedure. The study strengths is its relatively large population of 403 patients with complete questionnaire and outcome data at 12 months postop. The study has some significant limitations that affect our ability to utilize this information when counseling patients and limit the impact and applicability of the study.

A major limitation is the definition of failure and, within that, including patients who stopped OAB medication use prior to enrollment and then resumed after as MUS failures. In a MUI population the MUS should be expected to only address SUI symptoms since MUS treats SUI and not OAB. In this study treatment failure included patient undergoing any additional treatment for OAB or voiding dysfunction. In reviewing Table 3, the vast majority (88%, n=49) of subjective failures for additional urinary symptom treatment were patients who started medication or PTNS therapy for OAB/UII, 67% (n=32) of which were on OAB medication prior to enrollment. It is not surprising that patients on OAB meds, forced to stop due to study protocol, would then resume use postoperatively. It seems these patients should be excluded from the treatment failure definition. More importantly, MUS is not a treatment for OAB and thus additional treatment for OAB should almost be expected in a population with mixed incontinence undergoing continued care and clinical evaluation. Only 2 (4%) patients included in the additional urinary failure group actually underwent repeat therapy for SUI. These definitions thus seem to overestimate MUS treatment failure and, especially in the era of increased scrutiny for mesh MUS, the authors may want to consider highlighting these interpretations and limitations to ensure the data are not misinterpreted.

Specific comments:
- the objective specifies "undesired surgical outcomes" at 12 months, on initial read this would seem to include postoperative complications and adverse events, consider rewording for clarity.
- it seems that both OAB medication use, DO on UDS and higher irritative symptoms would be interrelated yet on logistic regression these were found to be independently associated with treatment failure, why do you think this is?
- lines 318-320, MUS is not a treatment for UII
- line 337, would state the actual difference per Table 1 was only 20mL.
The numbers below refer to manuscript line numbers.

P Values vs Effect Size and Confidence Intervals
While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, 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. This is true for the abstract as well as the manuscript, tables and figures.

Please provide absolute values for variables, in addition to assessment of statistical significance.

We ask that you provide crude OR’s followed by adjusted OR’s for all relevant variables.

Please limit p values to 3 decimal places.

Numbers below refer to line numbers

145: please make it clear that this is a secondary analysis of a trial. It is not at all clear from the abstract—the abstract needs to be able to stand alone. You may find that the reiteration of the results in the conclusion of the abstract can be deleted to give you more "word"s in the abstract to better describe your methods and conclusions.

152. The journal style does not support the use of the virgule ( / ) except in mathematical expressions. Please remove here and elsewhere.

149: you need to make at least a global statement about how the minimal clinically important difference on the UDI was decided. 26.1 seems a bit arbitrary.

156: most readers won’t know what a “Forced variable” is. Can you use a non-technical term in the abstract and in the manuscript explain it better?

161: on what tool is the urgency score measured?

179: you should probably mentions that the ESTEEM trial was a multicenter network trial.

184: Here and throughout, please note the comment by the statistical editor that you have not prospectively studied “predictors”–rather you are describing associations.

216: explain the 26.1, 10.2 and 5.4 scores as cutoffs for clinically important. This seems really arbitrary.

222 and similar portion of abstract: Remove the colon.

193: does this secondary analysis include women randomized to both treatment arms in the ESTEEM trial? Did you control for which arm the woman was randomized to?

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. 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.
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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.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the
3. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

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, references, 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. 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").
11. 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.

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   * A point-by-point response to each of the received comments in this letter.

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 30 days from the date of this letter. If we have not heard from you by Apr 25, 2020, we will assume you wish to withdraw the manuscript from further consideration.***

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

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2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

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