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.
Date: Jul 01, 2019
To: "Abigail Shatkin-Margolis"
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1036

RE: Manuscript Number ONG-19-1036

Self-Removal of a Urinary Catheter After Urogynecologic Surgery: A Randomized Non-Inferiority Trial

Dear Dr. Shatkin-Margolis:

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 Jul 22, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is a very important clinical question addressing a key postoperative issue for women undergoing urogynecologic surgery. I had a few comments / questions:

1. Lines 119-121, it is mentioned that “this has been our practice for 10-15 years and it has been proven to be a convenient strategy that appeases our patient population”. Then, in lines 310-11, “it has been the standard of care in our practice for 15 years and therefore is our benchmark for comparison”. I would recommend changing this to be consistent (either 10-15 years for both, or 15 years for both), and referencing it if this has been published previously.

2. Rates of UTI were very high in these two groups. Urine was routinely evaluated in all patients at 2- and 6-weeks. Were symptoms assessed, as well? How did you distinguish between asymptomatic bacteruria and UTI?

3. Lines 186-197. The primary aim was designed with a non-inferiority analysis. Secondary aims were analyzed with superiority, I assume. This should be stated.

Reviewer #2: Prospective, randomized non-inferiority trial comparing discontinuation of urinary catheter by patient for POUR versus removal in office after pelvic reconstruction surgery. Limitation is lack of diversity in patient population and unknown if same results would be obtained with different patient populations. Authors need to show how this study differs from those already published.

1. Line 66 - please define pelvic reconstructive surgery here (which procedures, etc.)

2. Line 69 - what is the time frame for this definition?

3. Line 81-83 - reference here

4. Line 80-83 - please provide more details here about the referenced study and how does the design and results of its findings differ from this study?

5. Line 85-86 - please support this with references, literature search, etc.

6. Line 101-104 - why were these procedures selected for the study?
7. Line 129-138 - what if the patient had trouble voiding after the initial 5 hours time frame after removal? Were they still considered as passed? Were all these patients seen at 2 weeks for the routine post-op visit?

8. Line 149-168 - was there a "stayed the same, no change" option in responses?

9. Line 278-279 - please clarify this sentence

10. Line 281 - please explain why this investigation is "unique"

11. Line 281-287 - staff time to answer increased number of phone calls from these patients is still a utilization of healthcare. How does amount of staff time to answer the increased number of phone calls compare with time saved from decreased office visits?

12. Line 309-310 - please explain/justify why routinely do 7 day use of catheter in these patients if it causes high rates of UTIs and is done for staff and patient convenience as opposed to medically indicated

Reviewer #3: This is a well designed and well written study. This is noninferiority randomized controlled trial between office discontinuation and self discontinuation of indwelling catheter after prolapse surgery. The primary outcome was POUR at one week. They found no difference in POUR at one week between these two methods. They found high patient satisfaction with no difference in adverse events. I will change my practice based on this study1

The strengths of this study include the study design, the inclusion of clinically important secondary outcomes and adverse events and patient experience outcomes.

This trial was registered at ClinicalTrials.gov. They did not report whether CONSORT guidelines were followed.

Below is a point-by-point critique

Introduction - adequate

Methods
1. Were CONSORT guidelines followed? Was the checklist completed?

Results
2. Table 1 lists a takeback to the OR, 4 readmissions and 8 other complications. What were these for? Were any related to POUR?

Discussion - adequate

Table 3
3. Are the VAS score means in mm or cm? The methods suggest that the VAS scale was a 100 mm scale so I would expect these measurements to be in mm, but they seem very low, ie everyone was happy with everything?

Figures
4. These figures are all important to the study. Figures 1 and 2 could be supplemental material if space limitations.

STATISTICAL EDITOR’S COMMENTS:

1. lines 54-55, 246-247: This seems like just a recapitulation of the randomization groups, since of course all the OD would have office visits. Should either omit from abstract or just state that 53.8% (42/78) of the SD group had provider encounters. No need for a stats comparison.

2. Table 1: Since these groups were randomized, there is no need to test for baseline differences in characteristics. Any differences (none found here) would be based on random chance.

3. lines 186-197, 241-243 and Tables: Should include a figure showing the non-inferiority margin and the results of the primary outcome analysis, ie, show the non-inferiority.

4. Tables 2 and 3: The NS results within the secondary outcomes and the patient experiences cannot be generalized, since there was no power/sample size analysis to verify how well negative findings could be discerned with the respective sample sizes and proportions or means being compared. Therefore, need to temper conclusions re: any negative findings, apart from the primary outcome.
5. Table 3: For question 1: the overall Chi-square was significantly different, and if pair-wise differences were tested (proportion improved, \( p = .002 \) by Fisher's test, favoring OD and \( p = 0.045 \) by Fisher's test, also favoring OD), so it seems those with SD were clearly not as satisfied with their after vs before symptoms. That needs to be included with the otherwise positive or neutral results from the SD vs OD groups.

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.

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. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the Methods section.

4. Tables, figures, and supplemental digital content should be original. The use of borrowed material (eg, lengthy direct quotations, tables, figures, or videos) is discouraged, but should it be considered essential, written permission of the copyright holder must be obtained. Permission is also required for material that has been adapted or modified from another source. Both print and electronic (online) rights must be obtained from the holder of the copyright (often the publisher, not the author), and credit to the original source must be included in your manuscript. Many publishers now have online systems for submitting permissions request; please consult the publisher directly for more information.

5. 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.

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 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.

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 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 appendices) but exclude references.

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).

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

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

10. Abstracts for all randomized, controlled trials should be structured according to the journal’s standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

11. 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.

12. 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.

13. 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.

14. The Journal’s Production Editor had the following to say about the figures in your manuscript:

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Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jul 22, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

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