OBSTETRICS & GYNECOLOGY

NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

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

**The corresponding author has opted to make this information publicly available.*

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: obgyn@greenjournal.org.

Date: Jul 19, 2019
To: "Sarah S Boyd" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1019

RE: Manuscript Number ONG-19-1019

Plug-unplug: a randomized controlled trial evaluating a novel approach to catheter management after pelvic reconstructive surgery

Dear Dr. Boyd:

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 Aug 09, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Overall: This is an original research report of an RCT comparing two different approaches of postoperative catheterization after prolapse surgery.

Overall the paper was well written and concise. The discussion is well written and compares and contrasts with existing literature. A weakness in the paper is not enough detail in the allocation and concealment process of randomization steps.

The abstract agrees with the manuscript.
The authors report no conflicts.
IRB/Ethics approval was obtained.
The RCT was registered and at clinicaltrials.gov and all details are provided.

If the authors used the CONSORT guidelines please state so and reference them.
CONSORT Statement: David Moher, Sally Hopewell, Kenneth F. Schulz, Victor Montori, Peter C. Gøtzsche, P.J. Devereaux, Diana Elbourne, Matthias Egger, Douglas G. Altman, CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials, Journal of Clinical Epidemiology, Volume 63, Issue 8, August 2010, Pages e1-e37, ISSN 0895-4356, http://dx.doi.org/10.1016/j.jclinepi.2010.03.004.
(http://www.sciencedirect.com/science/article/pii/S0895435610001034)

TITLE: Consider using the word compare in the title,

INTRODUCTION:
* If the authors had a hypothesis a priori please state it in the introduction
* Lines 85-87: Please make the objective match the objective stated in the methods.

MATERIALS AND METHODS:
* Please provide more detail about the allocation. Once the numbers were generated how was allocation and concealment done? Please use the CONSORT guidelines to ensure all components of these important steps are included.

RESULTS:
* The results section is concise. A weakness is the extensive use of acronyms that many obgyns may not be familiar with so it makes reading this section hard.

DISCUSSION:

* Please state the overall findings of your study in the context of your population and setting. Are there any differences in your enrolled 92 to the rest of the population?

TABLES AND FIGURES
* More detail is needed in the table titles so readers can understand the results without reading the text.
* Please be consistent with number of decimal points throughout so it's easier to compare numbers in the tables.

Reviewer #2: This is a randomized trial of continuous drainage (CD) vs plug-unplug (PUP) indwelling Foley catheter for management of acute postoperative voiding dysfunction following reconstructive pelvic surgery. Primary outcome was mean activity assessment score (AAS). 93 patients enrolled (32 PUP, 31CD, 30 no foley). The authors found no difference in AAS between the two groups. They conclude patients with PUP catheters perceive easier management and ability to complete ADLs with no added risk of adverse events despite no difference in postoperative mobility compared to CD catheters.

Overall this study presents an interesting alternative to CD bladder management postoperatively. The authors present the information but the results are somewhat difficult to understand due to the various comparisons (i.e. cath vs no cath, CD vs PUP and vs reference group) which makes the manuscript difficult to read and interpret/sift through the results/data. The overall rationale for the study structure is unclear - why do three groups as opposed to just comparing CD to PUP? And thus the relevance and takehome messages of the study get slightly convoluted. With revision and organization to clear points/results and comparisons, the manuscript would gain greater clarity and hopefully have a clearer message. Additionally, limit the strength of conclusions as this is small study underpowered for most of the outcomes reported as "no significant difference" so would be wary of strong conclusions.

Methods

1- why exclude posterior repair patients? These patients can still have postop retention and need acute catheterization.

2- please define "limited manual dexterity" and"history of neurologic condition affecting urinary function"

3- was there any blinding to randomization scheme or was randomization performed in blocks?

4- why not maintain randomization if they failed their void trial on POD5-7? how did you decide who got CD, PUP or CISC at that time?

5- for catheter impact assessment please ref here to figure. is this a validated questionnaire? Consider in future using validated catheter burden questionnaire.

6- can you provide range of AAS scores for reference for the reader (and whether higher is better or worse?)?

Results

7- line 191 please verify numbers reported are correct (18/32 =56.3% and 20/31=64.5%, also these are different than what is reported in table 2 for I think same outcomes).

8- why do you think the catheter groups had higher satisfaction with surgery/recovery? since catheterization is a significant burden would anticipate this would decrease satisfaction rates. how does this compare with other literature? how do you reconcile this with your finding that going home with UTI was "Greatly important" and 17 patients reported the catheter as worst part of their surgery?

9- the difference in healthcare visits from cath vs no cath, is that just related to their visits for postop void trial or did they also have high non-void trial related visits? Consider reporting as total # visits for each category/cohort.

10- for catheter impact would consider categorizing and comparing percentages by categories defined by the scale (i.e. low impact vs high impact) for more clinically relevant comparison, as current analysis stands it is unclear how clinically relevant a small difference between mean of a neutral response vs agree/disagree is for these questions.

11- consider just reporting complication rate as opposed to saying "low" - a 3month reoperation rate of 5/90 patients seems high. Consider adding a table with the postoperative complications and then putting in n for each group for clarity and completeness.

12- study was not powered to detect difference in LUTS between groups, consider revising wording/conclusions as a result

13- lines 235-238, please verify numbers as these do not seem to make sense. if 60% of all cath patients had UTI I would assume CD and PUP groups would have similar rates but reported that CD vs PUP each group had 80% UTI rate (the pooled result should thus around 80%). Also this is a VERY high UTI rate! Did you provide information on perioperative antibiotic administration (i.e only IV intraop or other antibiotics given)? Why such a high UTI rate do you think?

14- consider additional table with response by cohort to the preop and postop patient expectations (lines 239-245) as would be interesting to see individual group responses

Discussion

15- why did you choose to include UTI over 3 months? in methods consider adding how this was assessed, how you accounted for patients going to outside provider/urgent care for evaluation and why this time period is relevant to acute postop catheterization over the first postop week.

16- how do your results compare with the literature? Specifically Kandidai et al?

17- please expand on the limitations of your study (under powered for secondary outcomes, inability to blind participants/providers, etc.)

18- revise statement that patients with PUP found management easier and less prohibitive regarding ADL, this is via a non-validated questionnaire in under powered population with unclear clinical significance (again of a neutral to slightly agree/disagree response on the scale) so definitive conclusions cannot be made from this data. Also consider revising that there were no AE associated with this method as this was not powered for, you have small number of ~30 pts and thus no definitive conclusions can be made.

19- it is possible that having CD for longer period hampered the bladders contraction and thus doing void trial earlier in the CD patients would also have resulted in lower PVR as well, thus earlier void trials in all patients would likely be best recommendation especially given metanalysis data that <5 days is optimal for UTI prevention.

Tables/Figures

20. table 1 - how were symptoms of SUI and UUI assessed/defined?

21. table 2 - double check numbers as these are not consistent with what is reported in manuscript, why did so many patients get vaginal hysterectomy without suspension procedure? did you also include patients undergoing hyst for other reasons besides prolapse?

22. flow chart - very high decline rate for participation, why do you think this was the case? Did patients get any incentive for participation? Low recruitment is a limitation that should be clearly acknowledged

Reviewer #3: This is a randomized control trial "to compare impact on activity between two catheter management systems after failed voiding trial following pelvic reconstructive surgery."
Overall this paper is very well written and easy to follow. I have only minor suggestions. My suggestions for revisions are as follows:

1) I would like the authors to describe the PUP teaching that pts receive. Do they follow a schedule? Do they use a bag overnight?

2) The authors recognize that their primary outcome (AAS) may have been limited because of the period it was performed. Because this limitation was likely known a priori I would like the authors to spend a bit more time on how this primary outcome was chosen. I assume in part it's for patient centered outcome. But I think a stronger justification would help.

3) Why wasn't prior incontinence surgery excluded? In particular, I wonder how women who likely previously experienced a catheter might experience a repeat experience differently.

4) Did you look at any existing data on the risk of falls in women with CD versus PUP. If there is anything available on this I think it would good to add to paper.

5) Finally, did you find any literature on the current use of PUP? I think it may be helpful to reframe this trial as PUP an acceptable alternative although not necessarily superior to CD. It was powered as a superiority but could you look if PUP is non-inferior to CD (which I suspect is by far more commonly used). Then focus on the importance of giving patients options.

STATISTICAL EDITOR'S COMMENTS:

1. lines 38-40: Since the comparisons involved three groups, the inference threshold should be stricter than two-sided alpha = .05.

2. lines 41-42: All patients were not randomized, only the last 63 were. The first 30 (lines 37-38) comprised the reference

arm and were not chosen randomly, but rather assigned based on having passed the voiding trial. That is not randomization.

3. General: Need to be clearer re: the primary outcome and need to separate it from the various secondary outcomes. For example, is the primary the mean AAS score (post-op Total cited in Table 3)? Or is it the difference between pre and post total scores. Again, need to clearly separate it from the various subsets of secondary outcomes.

4. Table 1: Since this was a RCT, there is no need to provide stats tests of baseline characteristics. Any difference is thought to be due to random chance. The samples (N = 32 and 31) are modest. Were the distributions of age and BMI normal? If not, should cite as median(IQR or range) rather than as mean±SD. Given the sample sizes, should round the %s to nearest integer value.

5. Table 2: Same issue with normality re: length of procedure, post op hct, EBL and LOS and use of mean±SD vs median (IQR or range). Also, if non-normal, should then use non-parametric stats test. Given the sample sizes, should round the %s to nearest integer value.

6. Table 3: See previous comments re: separation of primary from secondary outcomes. Also, if the scale values were not normally distributed, then should cite as median(IQR or range) and test non-parametrically.

7. Table 4: Same issue as previously re: scores and whether the distributions were normal. Also, re: voided volume, PVR. Should round %s to nearest integer, since each denominator was ~ 30.

ASSOCIATE EDITOR - GYN COMMENTS:

Please revise the Title to better capture the study intent to the broad readership as 'Plug-Unplug' does not have immediate meaning to someone unfamiliar

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.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

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 manuscript's title page.

3. 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.

4. 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 article (after the References section).

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, references, tables, boxes, figure legends, and print appendixes) but exclude references.

8. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

9. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

10. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

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

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

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

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

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

15. 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%").

16. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

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

"Figure 2: Is this available at a higher resolution and in its original format (eps, tiff, jpeg, etc.)?"

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

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

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

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.

Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce.

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

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

***

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.

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 Aug 09, 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

time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.

[redacted]

Dear Editors:

Please find our attached revised manuscript newly titled, “A randomized controlled trial comparing two methods of catheter management after pelvic reconstructive surgery” for your re-consideration for publication as an original research article in Obstetrics and Gynecology.

Please publish our point-by-point response letter.

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

This manuscript has not been published elsewhere and I have verified the accuracy of the statements in the manuscript. All authors have made significant contributions to this research study.

I verify that permission has been obtained from all persons named in the acknowledgments.

Reviewer #1:
1. Overall: This is an original research report of an RCT comparing two different approaches of postoperative catheterization after prolapse surgery. Overall the paper was well written and concise. The discussion is well written and compares and contrasts with existing literature. A weakness in the paper is not enough detail in the allocation and concealment process of randomization steps.

Thank you for your comments. The allocation and concealment process is described in lines 117-119 (“Treatment allocation was made by a computer-generated random numbers table with permuted blocks of four and assigned at the time of patient consent. The surgical team was not blinded to group allocation.”). *Participants were consented at the time of their preoperative consultation and the computer-generated randomization using permuted blocks of four was performed at that time. The surgical team was not blinded as it was necessary to know group allocation for postoperative order placement. Participants understood that if they passed their initial inpatient voiding trial, they would not need a catheter upon discharge and would be allocated to the*

[redacted]

"reference group" and followed for the same amount of time as the experimental groups.

2. The abstract agrees with the manuscript. The authors report no conflicts. IRB/Ethics approval was obtained. The RCT was registered and at clinicaltrials.gov and all details are provided. If the authors used the CONSORT guidelines please state so and reference them.
CONSORT Statement: David Moher, Sally Hopewell, Kenneth F. Schulz, Victor Montori, Peter C. Gøtzsche, P.J. Devereaux, Diana Elbourne, Matthias Egger, Douglas G. Altman, CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials, Journal of Clinical Epidemiology, Volume 63, Issue 8, August 2010, Pages e1-e37, ISSN 0895-4356, http://dx.doi.org/10.1016/j.jclinepi.2010.03.004. (http://www.sciencedirect.com/science/article/pii/S0895435610001034)

*Thank you for your recommendation. Use of CONSORT guidelines has been added to the manuscript [lines 99-100, "*The trial was registered at ClinicalTrials.gov (#NCT03071211) and CONSORT (Consolidated Standards of Reporting Trials) guidelines were followed"*] with the reference.*

3. TITLE: Consider using the word compare in the title.

*The title has been modified, "*A randomized controlled trial comparing two methods of catheter management after pelvic reconstructive surgery"

4. INTRODUCTION: If the authors had a hypothesis a priori please state it in the introduction. Lines 85-87: Please make the objective match the objective stated in the methods.

*Thank you for your suggestion. We have added the hypothesis and modified the objective in lines 89-91: "*Our primary objective was to compare the impact on activity of PUP catheters to transurethral catheters with continuous drainage (CD) bag. We hypothesized that activity would differ between groups*."*

5. MATERIALS AND METHODS: Please provide more detail about the allocation. Once the numbers were generated how was allocation and concealment done? Please use the CONSORT guidelines to ensure all components of these important steps are included.

[redacted]

Randomization occurred at the time of preoperative consultation using a computer-generated random numbers table (www.randomization.com) with permuted blocks of 4 and there was no blinding.
Details of the randomization scheme have been added to lines 116-119.

6. RESULTS: The results section is concise. A weakness is the extensive use of acronyms that many obgyns may not be familiar with so it makes reading this section hard.

We appreciate the reviewer's comment. "PUP" and "CD" are acronyms that the authors have developed for the description of the two experimental arms and we have ensured they are defined at initial use. To make reading the results section easier, we have made sure to define all acronyms at initial use and verified that all acronyms besides "PUP" and "CD" are standardly accepted. Unfortunately, re-defining the acronyms again in the Results section would increase the word count above the maximum limit set by the journal. We would be happy to re-define the acronyms should the Editors allow.

7. DISCUSSION: Please state the overall findings of your study in the context of your population and setting. Are there any differences in your enrolled 92 to the rest of the population?

Baseline participant characteristics as shown in Table 1 reflect national characteristics described in women with pelvic organ prolapse and incontinence. The distribution of surgeries described in the manuscript (see Table 2) also reflects the distribution of procedures we perform clinically and to our knowledge is consistent with most well balanced urogynecology practices.

8. TABLES AND FIGURES: More detail is needed in the table titles so readers can understand the results without reading the text. Please be consistent with number of decimal points throughout so it's easier to compare numbers in the tables.

Table titles have been modified and numbers have been reviewed and modified for consistency and Green Journal requirements.

Reviewer #2: This is a randomized trial of continuous drainage (CD) vs plug-unplug (PUP) indwelling Foley catheter for management of acute postoperative voiding dysfunction following reconstructive pelvic surgery. Primary outcome

[redacted]

was mean activity assessment score (AAS). 93 patients enrolled (32 PUP, 31CD, 30 no foley). The authors found no difference in AAS between the two groups. They conclude patients with PUP catheters perceive easier management and ability to complete ADLs with no added risk of adverse events despite no difference in postoperative mobility compared to CD catheters.

1. Overall this study presents an interesting alternative to CD bladder management postoperatively. The authors present the information but the results are somewhat difficult to understand due to the various comparisons (i.e. cath vs no cath, CD vs PUP and vs reference group), which makes the manuscript difficult to read and interpret/sift through the results/data.

We appreciate the reviewer's comments and apologize for any difficulty reading the results. We have reworded the results section to the best of our ability.

2. The overall rationale for the study structure is unclear - why do three groups as opposed to just comparing CD to PUP? And thus the relevance and take home messages of the study get slightly convoluted.

We appreciate the reviewer's comments. While the main objective of this manuscript was to compare CD to PUP management of transurethral catheters, we also wanted to have a reference group of women that did not fail voiding trials and therefore did not require catheters. We felt it was important when assessing the level of discomfort or limitation in activity the experimental groups experienced that we indirectly controlled for the presence of the catheter itself by using a reference group.

By including the reference group, we were provided valuable information on the minimal impact of the presence of a catheter on activity and pain. This information is beneficial when counseling patients regarding expectations after pelvic reconstructive surgery and reassuring them that their activity level and discomfort is not affected by the presence of the catheter. Our current work and previous publications have shown increased patient anxiety regarding catheterization peri-operatively.

3. With revision and organization to clear points/results and comparisons, the manuscript would gain greater clarity and hopefully have a clearer message.

[redacted]

Additionally, limit the strength of conclusions as this is small study underpowered for most of the outcomes reported as "no significant difference" so would be wary of strong conclusions.

The conclusions in both the abstract and the manuscript have been modified.

4. Why exclude posterior repair patients? These patients can still have postop retention and need acute catheterization.

Thank you for your comments. It is true that posterior repair patients can experience urinary retention. We wanted to represent as uniform a population as possible and in our practice the length of stay after a posterior repair alone varies, and includes same day and overnight stay. Since we were studying inpatient population and the decision to keep or discharge the patient is sometimes made after the surgery we made the decision to exclude the small number of patients undergoing posterior repair alone.

5. Please define "limited manual dexterity" and “history of neurologic condition affecting urinary function"

*Definitions have been added to the manuscript lines 105-108: “*Patients discharged to nursing facilities, those with limited manual dexterity due to arthritis or other musculoskeletal disorder, or a history of a neurologic condition affecting urinary function such as Parkinson’s disease, spinal cord injury or multiple sclerosis were also excluded.”

6. Was there any blinding to randomization scheme or was randomization performed in blocks?

There was no blinding. Randomization was performed using computer-generated random numbers table in permuted blocks of four prior to implementation of the postoperative voiding trial. The randomization schema and group allocation description in the manuscript was modified to include these details (lines 116-119).

7. Why not maintain randomization if they failed their void trial on POD5-7? how did you decide who got CD, PUP or CISC at that time?

[redacted]

We considered maintaining the randomization when designing our study. The standard of care in our practice is to offer patients one of three management options at the time of voiding trial failure: plug-unplug, continuous drainage or clean intermittent self-catheterization (CISC). The majority of the patients are taught CISC, if they are able, as it allows to better monitoring of their voided volumes and has less risk of infection in published studies compared to transurethral catheters. We did not maintain the randomization past the first outpatient voiding trial as we did not want to alter our routine practice dramatically. Specifically we were not evaluating CISC in this study and felt introducing it would confuse the results.

8. For catheter impact assessment please ref here to figure. is this a validated questionnaire? Consider in future using validated catheter burden questionnaire.

The catheter impact questionnaire used in our study is not validated and this has been added to the manuscript. Figure 2 is referenced in lines 148-9 and 156.

Unfortunately, our study was IRB-approved and began enrollment prior to the publication of the study validating the Catheter Burden Questionnaire. We agree that future studies from our institution regarding impact of catheters should use this validated questionnaire.

Carpenter, et al in 2017, published the Short-term Catheter Burden Questionnaire (STCBQ) as a validated survey of catheter burden in pelvic reconstructive surgery patients. This 6-item survey is made of 2 sub-scales on embarrassment due to the catheter and difficulty of use with higher scores correlating to greater burden. Although our catheter impact questionnaire does not include an embarrassment component, some similarities with the STCBQ include questions regarding ease of use outside of home and ability to manage and wear discretely.

9. Can you provide range of AAS scores for reference for the reader (and whether higher is better or worse?)?

The range of AAS scores have been added to the manuscript, lines 146-147: "The total AAS score can range from 0-100 with higher scores reflecting better mobility." *The detailed description of scoring the AAS is also provided as supplementary digital content.*

[redacted]

10. Line 191 please verify numbers reported are correct (18/32 =56.3% and 20/31=64.5%, also these are different than what is reported in table 2 for I think same outcomes).

Thank you for this finding. Line 191 has been deleted as the information is repetitive and does not add any additional information not presented in Table 2. Table 2 has been reformatted to show prolapse and incontinence procedures first followed by hysterectomy numbers, given the population evaluated is a prolapse and incontinence population. Route of hysterectomy is reported as a percentage of the number of women that underwent hysterectomy (18/21, or 85.7% for vaginal hysterectomy in PUP and 20/31, or 64.5% in the CD arm).

11. Why do you think the catheter groups had higher satisfaction with surgery/recovery? Since catheterization is a significant burden would anticipate this would decrease satisfaction rates. How does this compare with other literature? How do you reconcile this with your finding that going home with UTI was "Greatly important" and 17 patients reported the catheter as worst part of their surgery?

*There was no difference in patient satisfaction across all groups (*PUP 78.1%, CD 80.0%, reference 66.7%, p=0.202)*.*

12. The difference in healthcare visits from cath vs no cath, is that just related to their visits for postop void trial or did they also have high non-void trial related visits? Consider reporting as total # visits for each category/cohort.

The number of healthcare visits was the total number of visits to the office after hospital discharge, including voiding trials. Unfortunately, category of chief complaint was not recorded.

13. For catheter impact would consider categorizing and comparing percentages by categories defined by the scale (i.e. low impact vs high impact) for more clinically relevant comparison, as current analysis stands it is unclear how clinically relevant a small difference between mean of a neutral response vs agree/disagree is for these questions.

Thank you for the comment. We will consider this for our future studies.

14. Consider just reporting complication rate as opposed to saying "low" - a

[redacted]

3month reoperation rate of 5/90 patients seems high. Consider adding a table with the postoperative complications and then putting in n for each group for clarity and completeness.

Given the space constraints, we did not add a table for 5 patients. If the editors deem this to be necessary, we will be happy to provide a table. The word "low" was removed.

15. Study was not powered to detect difference in LUTS between groups, consider revising wording/conclusions as a result

Thank you for this comment. We have modified this as seen in lines 309-310: "However, we were not powered to detect this difference."

16. Lines 235-238, please verify numbers as these do not seem to make sense. if 60% of all cath patients had UTI I would assume CD and PUP groups would have similar rates but reported that CD vs PUP each group had 80% UTI rate (the pooled result should thus around 80%). Also this is a VERY high UTI rate! Did you provide information on perioperative antibiotic administration (i.e only IV intraop or other antibiotics given)? Why such a high UTI rate do you think?

Thank you for bringing this to our attention. The numbers have been reviewed and modified in the abstract and manuscript. Line 53-55: "The catheter arms had significantly higher culture-positive UTI compared to the reference arm (58.7% vs. 6.7%, p<0.001). However, rate of UTI did not differ between catheter arms (PUP 68.8%, CD 48.4%, p=0.625)." Line 244-247: "Overall, 58.7% (37/62) of patients with postoperative catheters had culture-positive UTI compared to 6.7% (2/30) of patients without catheters (p<0.001). There was no difference in culture-positive UTI between patients with PUP catheters and CD catheters (PUP 68.8%, CD 48.4%, p=0.625)."

Information regarding preoperative antibiotics has been added to the Methods section, lines 119-121: "Patients randomized to catheter arms did not receive antibiotics during catheterization; however, all patients received appropriate pre-operative antibiotics, re-dosed if needed, per the guidelines".

We agree that the rate of UTI found in our cohort is much higher than anticipated and compared to the literature. This may be due to selection bias as those

[redacted]

discharged with a catheter underwent one additional visit to undergo their voiding trial, which provided an opportunity to assess urinary symptoms that the reference arm did not have. We found that although research staff were prompted to only send a urine culture if high clinical suspicion, urine cultures were sent on the majority of patients. We recognize that assessing symptoms of urethral discomfort, urgency may not be accurate in a catheterized patient. Furthermore, patients with a catheter may be colonized and by sending the urine culture we may be capturing bacteriuria that does not require treatment. As a result of this finding we are looking into evaluating and potentially changing our current practice.

Additionally we did not limit the diagnosis of UTI to only the duration of time the patients were catheterized. Rather, we reported the rate of UTI over the entire 3-month follow-up period, which may have contributed to our higher rate. Prior studies have also shown higher rates of UTI with transurethral catheterization greater than 5 days and the median duration of catheterization in our cohort was 7 days.

17. Consider additional table with response by cohort to the preop and postop patient expectations (lines 239-245) as would be interesting to see individual group responses

We would be happy to add this table if space permits and the editors deem it appropriate.

18. Why did you choose to include UTI over 3 months? in methods consider adding how this was assessed, how you accounted for patients going to outside provider/urgent care for evaluation and why this time period is relevant to acute postop catheterization over the first postop week.

As patients had the potential to have ongoing catheterization throughout the 3-month follow-up period, we intended to capture all episodes of UTI for the cohort throughout their duration of catheterization. While the cohort had a median duration of catheterization of 7 days (IQR 1-11), some patients in the cohort did continue CISC due to prolonged voiding dysfunction for upwards of 41 days (greater than 3rd quartile of patients).

Unfortunately, as patients were followed through review of electronic medical record at our institution as well as affiliated laboratories, and we did not

[redacted]

specifically assess for presentation at outside institutions during office visits or telephone calls, we are unable to report any additional evaluations for UTI outside of our institution.

19. How do your results compare with the literature? Specifically Kandidai et al?

While the primary objective of our study was impact on activity based on mean difference in AAS scores and secondary objectives included patient satisfaction and catheter impact, Kandadai, et al *assessed catheter-related pain and quality of life. Our findings were similar to their study in that patients with traditional transurethral catheters had lower overall scores when asked about impact on social activities and there was no difference between groups regarding catheter-related pain. However, our cohort did not differ significantly in overall satisfaction, while traditional catheter users scored worse in overall satisfaction in Kandadai et al's study. Additionally, our rate of culture-positive UTI was higher; however, we reported UTI across the 3-month follow-up period while Kandadai, et al. reported only UTI during catheterization.*

20. Please expand on the limitations of your study (under powered for secondary outcomes, inability to blind participants/providers, etc.)

*We have made the necessary corrections to lines 316-320: "*Timing of the postoperative AAS may have affected the scoring as it was administered between postoperative days 5-7 when patients are commonly instructed to restrict some of the activities assessed by the survey. Additional limitations include being underpowered for the secondary outcomes and the inability to blind participants or surgeons."

21. Revise statement that patients with PUP found management easier and less prohibitive regarding ADL, this is via a non-validated questionnaire in under powered population with unclear clinical significance (again of a neutral to slightly agree/disagree response on the scale) so definitive conclusions cannot be made from this data. Also consider revising that there were no AE associated with this method as this was not powered for, you have small number of ~30 pts and thus no definitive conclusions can be made.

*Conclusion revised (*lines 328-334): "With the current focus on patient-centered outcomes, it is important to continue to evaluate various postoperative management practices that may enhance patient recovery or satisfaction. Given

[redacted]

significant anxiety associated with requiring a catheter postoperatively, offering patients options when it comes to the catheter management is valuable. Plug-unplug catheter management technique is an acceptable method that does not appear to cause adverse events and may be considered for short-term catheterization after pelvic reconstructive surgery."

Conclusion in abstract also revised (lines 56-61): "Activity does not differ in patients discharged with PUP or CD catheters, but those with PUP perceive easier management and ability to complete activities of daily living with no added risk of adverse events. Future studies using validated questionnaires on catheter impact are necessary to definitively assess catheter burden due to the PUP method. PUP is an acceptable alternative to traditional catheterization after pelvic reconstructive surgery."

22. It is possible that having CD for longer period hampered the bladders contraction and thus doing void trial earlier in the CD patients would also have resulted in lower PVR as well, thus earlier void trials in all patients would likely be best recommendation especially given metanalysis data that <5 days is optimal for UTI prevention.

Thank you for your comment. We agree. In our cohort both groups were offered repeat voiding trials at similar time intervals (between postoperative days 5 and 7) with median duration of catheterization 7 days (meaning both groups underwent a repeat voiding trial by postoperative day 7) and yet the PUP group had lower PVR and higher voided volumes at the time of that repeat voiding trial compared to the CD group. Hence, we hypothesized that the voiding function may be less inhibited in the PUP group.

23. Table 1 - how were symptoms of SUI and UUI assessed/defined?

Patients were recorded to have symptoms of SUI and UUI if they reported urinary symptoms that met the standard International Continence Society definition of SUI (involuntary leakage of urine with increased abdominal pressure) or UUI (involuntary leakage of urine associated with strong desire to urinate) during the initial consultation.

24. Table 2 - double check numbers as these are not consistent with what is reported in manuscript, why did so many patients get vaginal hysterectomy without suspension procedure? did you also include patients undergoing hyst for

other reasons besides prolapse?

Thank you for this finding. The table 2 values were reviewed and are correct. The route of hysterectomy is reported as a percentage of the total number of women in the cohort that underwent hysterectomy. For example, 21 women in the PUP arm underwent hysterectomy, of which 18/21 underwent vaginal hysterectomy, or 85.7%. The manuscript text has been deleted as it is not pertinent to the subject presented and there was no difference in surgical characteristics between arms. Line 202-203: "There were no differences in surgical characteristics between PUP and CD users."

As this was a prolapse and incontinence population, we have reformatted table 2 to reflect prolapse and incontinence procedures first, followed by any other concomitant procedures (e.g., hysterectomy). All patients in the cohort underwent an apical prolapse procedure. Not everyone in the cohort underwent a hysterectomy as the population included patients that had a history of prior hysterectomy (12.5% of PUP arm, 9.7% of CD arm) or desired uterine conservation (although the latter was not specifically recorded).

25. Flow chart - very high decline rate for participation, why do you think this was the case? Did patients get any incentive for participation? Low recruitment is a limitation that should be clearly acknowledged

When assessed 466 women undergoing surgery in the practice for eligibility in the study. Of those women, 293 (62.9%) consented to participate in the surgery, which we consider an adequate participation rate. 16 women were withdrawn prior to the implementation of the voiding trial, leaving 277 women that underwent the voiding trial.

Subjects were not incentivized to participate in the study.

Additionally, as per our institution's IRB requirements, we were require to disclose the standard of care in our practice to all patients that went through the consent process. As our standard of care is to utilize PUP management of catheters, the majority of patients that declined to participate preferred our usual management with no change to their clinical care.

Reviewer #3: This is a randomized control trial "to compare impact on activity between two catheter management

systems after failed voiding trial following pelvic reconstructive surgery."
Overall this paper is very well written and easy to follow. I have only minor suggestions. My suggestions for revisions are as follows:

Thank you for your positive comments.

1) I would like the authors to describe the PUP teaching that pts receive. Do they follow a schedule? Do they use a bag overnight?

We specify plug-unplug teaching in the Methods section of the manuscript. Patients were instructed to unplug the catheter every 4 hours or when they felt the urge to void. All patients with catheters, regardless of PUP or CD, were offered a large drainage bag for overnight drainage. Lines 122-126:

"The catheter arms had a 16-French transurethral catheter attached to either a leg bag (CD arm) or capped with a plastic plug (PUP arm) and instructed to uncap when they felt the urge to void, or in the absence of urge, at least every four hours (Figure 1). Patients in both groups were provided a large drainage bag for gravity-based drainage for overnight use."

2) The authors recognize that their primary outcome (AAS) may have been limited because of the period it was performed. Because this limitation was likely known a priori I would like the authors to spend a bit more time on how this primary outcome was chosen. I assume in part it's for patient centered outcome. But I think a stronger justification would help.

The manuscript has been modified to reflect justification of use (lines 276-282)

"Although we anticipated this possibility *a priori*, we specifically were looking for a patient-centered outcome as we hypothesized that the choice of catheter was unlikely to affect any clinical outcomes but may demonstrate difference in patient's mobility and/or satisfaction. We specifically chose to use the AAS due to its use in prior studies and validation in urogynecologic population. Additionally, it is made of 3 subscales that allowed additional comparisons based on the type of activity (e.g., sedentary, ambulatory or work/exercise)."

3) Why wasn't prior incontinence surgery excluded? In particular, I wonder how women who likely previously experienced a catheter might experience a repeat

[redacted]

experience differently.

We felt it was important to include women with prior incontinence procedures for this very reason—their prior experience may have been different than current experience and we wanted to represent these women within our population studied.

4) Did you look at any existing data on the risk of falls in women with CD versus PUP. If there is anything available on this I think it would good to add to paper.

Thank you for this interesting question. In our literature search, we did not find any data regarding the practice of PUP; therefore, fall risk with the PUP is unclear. There were no falls identified in either of our cohort of patients, which was arguably too small to capture these events. However, although an extrapolation, given patients with PUP found the catheter easier to manage, we would hypothesize that decreasing fall risk during catheterization may be possible with PUP catheters versus a traditional drainage bag. This would be an interesting outcome to evaluate in future studies.

5) Finally, did you find any literature on the current use of PUP? I think it may be helpful to reframe this trial as PUP an acceptable alternative although not necessarily superior to CD. It was powered as a superiority but could you look if PUP is non-inferior to CD (which I suspect is by far more commonly used). Then focus on the importance of giving patients options.

Thank you for your comments. As stated above, our literature search provided no evidence of the use of PUP, while our practice has been performing it routinely for over 20 years. This was the impetus for our RCT. Our conclusion has been modified to reflect the technique as an acceptable alternative.

This was not a superiority trial; therefore, we cannot report superiority of the PUP to CD and we did not report our conclusions as such.

Developing a non-inferiority trial comparing PUP to CD is something we look forward to pursuing in the future if possible.

We wholeheartedly agree that it is important to offer patients options. We added the following to our conclusion:

[redacted]

“With the current focus on patient-centered outcomes it is important to continue to evaluate various postoperative management practices that may enhance patient recovery or satisfaction. Given significant anxiety associated with requiring a catheter postoperatively, offering patients options when it comes to the catheter management is valuable.”

STATISTICAL EDITOR'S COMMENTS:

1. lines 38-40: Since the comparisons involved three groups, the inference threshold should be stricter than two-sided alpha = .05.

The primary outcome was based on a comparison of two arms. The reference group is used in a comparison of with vs. without the catheter. Using a two-sided alpha of 0.05 is correct, and so we respectfully decline this suggestion.

2. lines 41-42: All patients were not randomized, only the last 63 were. The first 30 (lines 37-38) comprised the reference arm and were not chosen randomly, but rather assigned based on having passed the voiding trial. That is not randomization.

All patients were randomized at the pre-operative visit when enrolled, prior to undergoing their surgery and postop voiding trial. They understood if they did pass the voiding trial, they would then be assigned to the reference group of women discharged without a catheter for comparison with those that were discharged with catheters. This has been clarified in lines 116-118 and 126-130:

“Participants were randomized at enrollment 1:1 to one of two arms: CD or PUP. Treatment allocation was made by a computer-generated random numbers table with permuted blocks of four and assigned at the time of patient consent. The surgical team was not blinded to group allocation…Subjects enrolled and randomized who passed the inpatient VT, and therefore did not require a catheter, were assigned to a reference arm, which was assessed using the same pre- and post-operative questionnaires as the catheter arms. Once the reference arm reached the predetermined enrollment requirement, any subsequent patient who was enrolled in the study but passed her inpatient VT was excluded.”

3. General: Need to be clearer re: the primary outcome and need to separate it from the various secondary outcomes. For example, is the primary the mean AAS score (post-op Total cited in Table 3)? Or is it the difference between pre

and post total scores. Again, need to clearly separate it from the various subsets of secondary outcomes.

The primary and secondary outcomes have been re-stated at the beginning of the statistics section in "methods" to clarify (lines 164-166).

"The primary outcome was activity measured by difference in scores between arms on the AAS. Secondary outcomes included rate of UTI, time to passing outpatient VT in days, postoperative pain, patient satisfaction and catheter impact (figure 2)."

4. Table 1: Since this was a RCT, there is no need to provide stats tests of baseline characteristics. Any difference is thought to be due to random chance. The samples (N = 32 and 31) are modest. Were the distributions of age and BMI normal? If not, should cite as median(IQR or range) rather than as mean±SD. Given the sample sizes, should round the %s to nearest integer value.

We respectfully disagree. We believe it is important to describe baseline demographic and clinical characteristics to define the sample/population, as is done is almost all clinical trials. Additionally, reporting of baseline characteristics for the population is also a CONSORT requirement. For normality of distribution, all data were evaluated and all tests reflect proper application of statistics based on whether the distributions were normal or non-parametric.

5. Table 2: Same issue with normality re: length of procedure, post op hct, EBL and LOS and use of mean±SD vs median (IQR or range). Also, if non-normal, should then use non-parametric stats test. Given the sample sizes, should round the %s to nearest integer value.

We offer the same answer as above for evaluation of distribution(s) and application of statistical tests.

6. Table 3: See previous comments re: separation of primary from secondary outcomes. Also, if the scale values were not normally distributed, then should cite as median(IQR or range) and test non-parametrically.

Scale values were normally distributed.

[redacted]

7. Table 4: Same issue as previously re: scores and whether the distributions were normal. Also, re: voided volume, PVR. Should round %s to nearest integer, since each denominator was ~ 30.

Scores were normally distributed.

ASSOCIATE EDITOR - GYN COMMENTS:

Please revise the Title to better capture the study intent to the broad readership as 'Plug-Unplug' does not have immediate meaning to someone unfamiliar

The title has been modified.

PRODUCTION EDITOR COMMENTS:

Figure 2: Is this available at a higher resolution and in its original format (eps, tiff, jpeg, etc.)?
This figure has been added to the submission in its original format.

Thank you for your consideration and thoughtful, constructive comments.

Sincerely,

Sarah S. Boyd, MD