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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*
- Email correspondence between the editorial office and the authors*

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

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Questions about these materials may be directed to the Obstetrics & Gynecology editorial office:

obgyn@greenjournal.org.
RE: Manuscript Number ONG-18-1692

COMPARING TWO VOIDING TRIALS AFTER PELVIC ORGAN PROLAPSE RECONSTRUCTION: A RANDOMIZED CONTROLLED TRIAL

Dear Dr. Pilkinton:

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 Nov 01, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: MANUSCRIPT NUMBER: 18-1692

TITLE: Comparing two voiding trials

Overall: This is an report of a randomized clinical trial comparing two different approaches to voiding trials after pelvic organ prolapse surgery. The authors allocated women to receive either Force of Stream voiding trial or Standard Voiding Trial. There are inconsistencies in the report as well as inconsistencies between the report and what is posted on clinicaltrials.gov. the inconsistencies made the manuscript hard to follow. Additionally, if the authors used the CONSORT guidelines for study planning as well as reporting the guidelines should be cited.


IRB/Ethics approval was obtained
The trial was registered on ClinicalTrials.gov. The date of receiving documents as posted on the website is April 12, 2016 which is about the same time enrollment started.

The title as stated on ClinicalTrials.gov is more clear and more accurate than the title on the manuscript. Comparing Force of Stream to Retrograde Fill Voiding Trial After Vaginal Apex Suspension

The primary outcome stated on ClinicalTrials.gov is also more succinct and clear than what is written in the manuscript. Rate of catheterization within the six-week post-operative period following surgical repair of prolapse, among those discharged without a urinary catheter. [ Time Frame: 6 weeks ]

INTRODUCTION:

1. The introduction leads fairly well into the aims for the trial. But the wide use of acronyms makes it hard for readers not familiar with the trial to read the introduction easily.

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MATERIALS AND METHODS:

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5. Lines 165: Why conduct a regression for an RCT? This can't really be done in an RCT because any other characteristics associated with failing a voiding trial should have been randomized out in the two groups.

RESULTS:

6. The participant flow chart should follow precisely the CONSORT model.

7. The analysis groups have almost 20 fewer participants, each, than the number allocated to the group. The math doesn't add up.

8. Clarify if this was intent to treat.

9. Clarify if women were enrolled and allocated at the same time or at different times?

DISCUSSION:

10. Please state the overall findings of your study in the context of your population and setting. Currently the overall findings are buried in the first paragraph of the discussion.

11. Use the Green Journal’s writing guide to assist with writing a good discussion. edmgr.ovid.com/ong/accounts/guidetowriting.pdf

12. To whom are results generalizable?

TABLES AND FIGURES

13. The titles for tables and figures should be descriptive enough that they can stand alone and readers can obtain important information without having to read the text.

14. If acronyms are used in tables the full definition should be stated in footnotes for the tables.

15. Include the number of persons in each group in the tables.

16. Figure 1 the protocol flow is not necessary

Reviewer #2: This is a study that identified a need in the postoperative Urogynecologic patient population. One of my concerns is its applicability to the general readership of the journal.

1. The authors state the following: "in the FOS arm, if she reported the FOS via VAS scale >/= 50, she voided successfully. If the FOS was 49 or less, a PVR was measured via bladder ultrasound. If PVR was less than 500mL, she was deemed as passing the FOS; otherwise if PVR greater than 500mL, she was deemed as having failed the FOS and was discharged with a catheter." Why was an inaccurately reported FOS of 49 or less deemed successful as long as the PVR was measured to be <500? This seems confusing. A PVR of <500cc but more than 200 seems like the patient would have failed and should go home with a catheter. I'm confused about these values for the FOS arm? How did the authors come up with these cutoffs?

2. In the verbage of the results section, I would use less words for text and ideas that are already represented in tables and figures. It will make the whole section more concise.

3. Seventy one subjects (83%) in the FOS group and 64 subjects (74%) in the SVT group passed the TOV at the time of discharge -- was this similar or different? It seems important to report this clearly, as I wonder if the number of patients going home with a catheter after surgery is not different between the groups (as this focuses on why the study was done in the first place ... i.e. to decrease number of catheters going home as both marker of VD ultimately and patient satisfaction intitially)

4. Table 2 is not really surgical "outcomes" -- perhaps "surgical characteristics" or something like that?

Table 3. What is FOS reported?
Reviewer #3: The authors present a non-inferiority randomized controlled trial comparing voiding trial techniques following apical prolapse surgery. The techniques are urinary force of stream method and standard fill voiding trial. The primary outcome was the rate of catheterization for voiding dysfunction within 6 weeks in those subjects who successfully voided at discharge. Secondary endpoints included TOV failure rates, incidence of urinary tract infections, and questionnaire symptom scores (UDI-6 and AUASS) postoperatively.

I applaud the authors for tackling such a clinically relevant question. I am often asked by residents and colleagues about the best choice for performing a voiding trial after prolapse surgery. I am also impressed with the number of variables taken into consideration which may influence a patient’s ability to void.

Suggestions and comments:

1. The manuscript is somewhat dense and difficult to read and could use some grammatical polishes.

2. Line 29: postoperative instead of "postop"

3. Line 32 and 33 describe the technique of the force of stream method as "Successful voiding criteria in the FOS group was subjective FOS >50 using a visual analog scale. Reporting <50 prompted a bladder scan and successful voiding was defined by a PVR <500mL.

4. Line 141 - 143: If PVR was less than 500mL, she was deemed as passing the FOS; otherwise if PVR 500mL, she was deemed as having failed the FOS and was discharged with a catheter.

5. A post-void residual of 500 mL is greater than the traditionally accepted PVR of 150 mL used for indicating voiding dysfunction or obstruction (ACOG CO 603 ). This large amount of PVR was initially difficult for me to accept as a useful amount for making the decision to send the patient home with a catheter or not, however as is later discussed in the article, using such a liberal amount may result in fewer catheterizations that were not required and fewer UTI’s. I would like to have seen more information about the decision to use a cut-off of 500 mL.

6. Line 38: TOV is used but was not defined previously (trial of void (TOV) is given on line 69) - suggest defining this on line 38 instead of 69.

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11. Line 145: Prescribed antibiotics for UTI prophylaxis was based on surgeon discretion with some providing daily antibiotic prophylaxis while catheter in situ, some prescribing a treatment course after catheter removed indefinitely, and some not providing any antibiotics unless symptomatic.

12. One of the secondary outcomes was UTI - more details concerning a comparison of patients receiving or not receiving antibiotics who went on to develop a UTI would be useful.

STATISTICAL EDITOR’S COMMENTS:

1. line 55-56: The conclusion should include the primary outcome, using the language of non-inferiority, which is how the hypothesis was stated and how the conclusion should be cited. The proportion discharged with a catheter is a numerical difference, no statistical comparison was provided (there would be NS difference). There was no power analysis to discern safety and it would be difficult to generalize safety findings from samples of these sizes.

2. lines 161-162: Need to justify choice of 10% as the non-inferiority margin.

3. lines 198: How does this p value (< .01) relate to the conclusion? The margin is clearly non-inferior vs the margin of 10%.

4. lines 200, : What is the meaning of p < 1.0? There is apparently no difference.
5. lines 205-206, 207-208: What is the meaning of p < 0.2 or p < 0.21? There is no statistical difference.

6. line 211: How does p < 0.02 relate to Fig 3? And if there was no difference, then why is p < .02?

7. lines 212-216: There were too few cases of VT failure to test for 12 variables. Were the age and pain score unadjusted or adjusted ORs? Should state the index used for age (ie, was this per year). Also, was the OR of 1.43 per year of age?

8. lines 222-225: Were the AUA-SS and UDI-6 scores normally distributed? If not, then should cite as median (IQR or range), not as mean± SD and the comparisons should use non-parametric testing.

9. lines 223, 225, 227, 229: Why were the p values formatted as p < non significant values?

10. Should clearly identify the primary outcome in Table of results and separate it from the secondary outcomes and cite the primary in terms of non-inferiority testing.

11. Table 1: Since this was a RCT, no need to statistically compare the baseline characteristics. However, it is unfortunate that the randomization did not include blocks of prolapse stage, since the cohorts differed in distribution of Stages of apical prolapse, which may complicate interpretation of results.

12. Table 3: Need to cite p value for first row entry, other than < 0.3, should be a value.

13. Fig 3: Should enter the "n" remaining in each cohort at appropriate intervals along the x-axis.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
   1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
   2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. This statement must appear at the end of your Materials and Methods section. 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). Examples of statements can be found online at http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf.

3. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at http://links.lww.com/AOG/A515, and the gynecology data definitions are available at http://links.lww.com/AOG/A935.

4. 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 appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

5. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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 Obstetrics & Gynecology, please indicate this in your acknowledgments.
Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

6. 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.

7. 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.

8. 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.

9. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

10. Our readers are clinicians and a detailed review of the literature is not necessary. Please shorten the Discussion and focus on how your results affect or change actual patient care. Do not repeat the Results in the Discussion section.

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.

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

"Figure 3 – Author needs to submit figure as a high-res (at least 300 DPI) image file (JPEG, EPS, TIFF)"

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 (e.g., 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.

Figures should be no smaller than the journal column size of 3 1/4 inches. Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce. Refer to the journal printer's web site (http://cjs.cadmus.com/da/index.asp) for more direction on digital art preparation.

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

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

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 Nov 01, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology
2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

In response to the EU General Data Protection Regulation (GDPR), you have the right to request that your personal information be removed from the database. If you would like your personal information to be removed from the database, please contact the publication office.

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Dear Editors and reviewers of Obstetrics & Gynecology,

Thank you for the opportunity to edit and respond to your comments. Please see our responses in red below.

Sincerely,

Marjorie Pilkinton

RE: Manuscript Number ONG-18-1692

COMPARING TWO VOIDING TRIALS AFTER PELVIC ORGAN PROLAPSE RECONSTRUCTION: A RANDOMIZED CONTROLLED TRIAL

REVIEWER COMMENTS:

Reviewer #1: MANUSCRIPT NUMBER: 18-1692

TITLE: Comparing two voiding trials

Overall: This is an report of a randomized clinical trial comparing two different approaches to voiding trials after pelvic organ prolapse surgery. The authors allocated women to receive either Force of Stream voiding trial or Standard Voiding Trial. There are inconsistencies in the report as well as inconsistencies between the report and what is posted on clinical trials.gov. The inconsistencies made the manuscript hard to follow. Additionally, if the authors used the CONSORT guidelines for study planning as well as reporting the guidelines should be cited.


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The title as stated on ClinicalTrials.gov is more clear and more accurate than the title on the manuscript. Comparing Force of Stream to Retrograde Fill Voiding Trial After Vaginal Apex Suspension

The title has been changed to reflect this critique.

The primary outcome stated on ClinicalTrials.gov is also more succinct and clear than what is written in the manuscript. Rate of catheterization within the six-week post-operative period following surgical repair of prolapse, among those discharged without a urinary catheter. [Time Frame: 6 weeks]

Corrections made for this comment.

INTRODUCTION:

1. The introduction leads fairly well into the aims for the trial. But the wide use of acronyms makes it hard for readers not familiar with the trial to read the introduction easily.

   The authors have made changes to limit the number of acronyms.

2. Line 91: Was this a safety and efficacy trial or a clinical RCT comparing two types of voiding trials?
Corrections were made to clarify this study as an RCT of two voiding trials.

3. Did all the procedures vaginal apex suspension?

All participants underwent surgical correction of the vaginal apex through various surgical means, either suspension or obliterative, with the majority undergoing a suspension.

MATERIALS AND METHODS:

4. Line 152-154: Please state clearly how this statement relates to the statement as outcome on clinicaltrials.gov. Passing a trial and leaving without a catheter may not mean the same thing.

Corrections made to primary outcome statement to closely follow the outcome listed on clinicaltrials.gov

5. Lines 165: Why conduct a regression for an RCT? This can't really be done in an RCT because any other characteristics associated with failing a voiding trial should have been randomized out in the two groups.

We conducted the regression analysis as a post-hoc analysis (i.e. this analysis to examine covariates was not pre-specified in the protocol or at the design stage of the study). We agree with the reviewer that in theory, proper randomization in a RCT is expected to balance treatment groups with respect to patient characteristic and covariate levels on average, and while it is not unusual to observe imbalances post hoc, these imbalances or differences between arms may be attributable to a 'type I' error or a random phenomenon. We have therefore decided to remove all reference to this post-hoc analysis. The manuscript has been appropriately revised.

RESULTS:

6. The participant flow chart should follow precisely the CONSORT model.

Changes made to chart to better reflect CONSORT model.

7. The analysis groups have almost 20 fewer participants, each, than the number allocated to the group. The math doesn't add up.

Our primary analysis includes those subjects who passed their voiding trial. In the FOS group, 71 of 86 subjects passed and therefore were included in the primary analysis. In the SVT group, 64 of 87 passed their TOV and were included in the primary analysis. Therefore, to the above comment, the decrease in number of participants observed as compared to the number allocated to each group is a reflection of excluding those subjects who failed their voiding trials and thus were excluded from the primary outcome.

8. Clarify if this was intent to treat

Corrections made to include this statement in the methods section

9. Clarify if women were enrolled and allocated at the same time or at different times?

Corrections made to clarify in the methods section.

DISCUSSION:

10. Please state the overall findings of your study in the context of your population and setting. Currently the overall findings are buried in the first paragraph of the discussion

Changes made accordingly.

11. Use the Green Journal's writing guide to assist with writing a good discussion. edmgr.ovid.com/ong/accounts/guidetowriting.pdf

Changes made accordingly.

12. To whom are results generalizable?

Changes made accordingly.

TABLES AND FIGURES
13. The titles for tables and figures should be descriptive enough that they can stand alone and readers can obtain important information without having to read the text. We appreciate the suggestion. Edits have been made to improve titles.

14. If acronyms are used in tables the full definition should be stated in footnotes for the tables. Footnotes added.

15. Include the number of persons in each group in the tables. Changes made accordingly.

16. Figure 1 the protocol flow is not necessary. We appreciate this critique. We believe the flow diagram will aid readers in understanding the algorithms for the 2 voiding trials given that FOS is likely unfamiliar to most readers. The diagram would ensure reader understandability of the trial’s intervention protocols. If the reviewers would prefer, we could downsize the flow diagram to only include the FOS protocol since that is likely more unfamiliar to readers than SVT.

Reviewer #2: This is a study that identified a need in the postoperative Urogynecologic patient population. One of my concerns is its applicability to the general readership of the journal.

1. The authors state the following: “in the FOS arm, if she reported the FOS via VAS scale >/= 50, she voided successfully. If the FOS was 49 or less, a PVR was measured via bladder ultrasound. If PVR was less than 500mL, she was deemed as passing the FOS; otherwise if PVR greater than 500mL, she was deemed as having failed the FOS and was discharged with a catheter.” Why was an inaccurately reported FOS of 49 or less deemed successful as long as the PVR was measured to be <500? This seems confusing. A PVR of <500cc but more than 200 seems like the patient would have failed and should go home with a catheter. I’m confused about these values for the FOS arm? How did the authors come up with these cutoffs?

These values in question and the force of stream protocol was based on the original force of stream protocol reported by Ingber (Ingber MS, Vasavada SP, Moore CK, Rackley RR, Firooz F, Goldman HB. Force of stream after sling therapy: safety and efficacy of rapid discharge care pathway based on subjective patient report. J Urol 2011;185:993-7.) We felt it important to follow the original protocol for reporting consistency and adding to the literature on force of stream voiding trials. If we varied from the original force of stream protocol, we believed this would only create more variations in published voiding trials. Limiting variations in protocols, publishing on one specific protocol in various clinical scenarios adds to the literature on force of stream first published by Ingber. Consistency in conducting and reporting force of stream strengthens our understanding of the utility of the voiding trial.

2. In the verbage of the results section, I would use less words for text and ideas that are already represented in tables and figures. It will make the whole section more concise.

We appreciate the suggestion. Changes made to reflect this suggestion.

3. Seventy one subjects (83%) in the FOS group and 64 subjects (74%) in the SVT group passed the TOV at the time of discharge -- was this similar or different? It seems important to report this clearly, as I wonder if the number of patients going home with a catheter after surgery is not different between the groups (as this focuses on why the study was done in the first place ... i.e. to decrease number of catheters going home as both marker of VD ultimately and patient satisfaction intitiially).

In the manuscript, we presented the following: ‘There was no significant difference between the two groups for patients who failed TOV and required catheterization at discharge (FOS, 17.4% [15/86] vs SVT, 26.4% [23/87], RR, 0.65; 95% CI 0.37 to 1.18, p=0.2).’ which addresses the concern the of the reviewer. This information was part of our secondary analysis. Despite a non-significant finding, we were pleased to see the FOS trended towards a lower TOV failure rate than SVT. Nonetheless, we acknowledge the study was not powered to detect differences in catheterization at discharge between the two trials. Our primary outcome was catheter reinsertion for voiding dysfunction in those discharged without a catheter. We believe the primary outcome chosen was the most important aspect in examining any voiding trial’s validity. If a voiding trial has a low failure rate but a high rate of catheter reinsertions for voiding dysfunction postoperatively, our opinion is that the voiding trial is not identifying
voiding dysfunction well enough. We were pleased to see that the FOS trial was non-inferior to SVT in catheter reinsertion for voiding dysfunction in those discharged without a catheter. A future trial is necessary to detect differences in catheterization rates at discharge between the two trials.

4. Table 2 is not really surgical "outcomes"—perhaps "surgical characteristics" or something like that?

Changes made accordingly.

Table 3. What is FOS reported?

This is the subjective force of stream (FOS) reported by the patients using the visual analog scale after voiding during their trial of void. In the table, the median FOS reported in each group was 80. This value was collected for all subjects in the trial but the reported FOS was only considered in the algorithm of catheter management in the FOS group was per the voiding trial protocol in FIGURE 1. A footnote explanation was added to the table.

Reviewer #3: The authors present a non-inferiority randomized controlled trial comparing voiding trial techniques following apical prolapse surgery. The techniques are urinary force of stream method and standard fill voiding trial. The primary outcome was the rate of catheterization for voiding dysfunction within 6 weeks in those subjects who successfully voided at discharge. Secondary endpoints included TOV failure rates, incidence of urinary tract infections, and questionnaire symptom scores (UDI-6 and AUASS) postoperatively.

I applaud the authors for tackling such a clinically relevant question. I am often asked by residents and colleagues about the best choice for performing a voiding trial after prolapse surgery. I am also impressed with the number of variables taken into consideration which may influence a patient's ability to void.

Suggestions and comments:

1. The manuscript is somewhat dense and difficult to read and could use some grammatical polishes.

   The authors have tried to edit to improve readability or the manuscript.

2. Line 29: postoperative instead of "postop"

   Changes made accordingly.

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5. A post-void residual of 500 mL is greater than the traditionally accepted PVR of 150 mL used for indicating voiding dysfunction or obstruction (ACOG CO 603) This large amount of PVR was initially difficult for me to accept as a useful amount for making the decision to send the patient home with a catheter or not, however as is later discussed in the article, using such a liberal amount may result in fewer catheterizations that were not required and fewer UTIs. I would like to have seen more information about the decision to use a cut-off of 500 mL.

   The cutoff of 500mL was initially evaluated in the original force of stream study by Ingber et al. in which the authors used a 500mL limit for allowable postvoid residual. In an effort to perform the force of stream voiding trial consistently with the original study, the authors decided not to decrease the PVR postvoid residual limit despite the same concerns the reviewer is expressing. But reassuringly our data showed that this higher PVR threshold may ultimately lead to less catheters with no greater risk of urinary tract infection or re-catheterization. In addition, urinary symptoms improved postoperatively in the entire study population. However, we did not analyze separately the urinary symptom scores of those with markedly elevated PVR.

6. Line 38: TOV is used but was not defined previously (trial of void (TOV) is given on line 69) - suggest defining this on line 38 instead of 69.
Changes made accordingly.

7. Line 56-57 and : The association of age and pain with failure of a voiding trial is a finding of this study that adds to the clinical relevance of the work.

This analysis was excluded from the main results manuscript, per suggestion of the majority of reviewers.

8. Line 110: “Concomitant procedures including hysterectomy, synthetic midurethral slings, and anterior/posterior colporrhaphy were allowed.”

9. I would like to have seen more detail concerning the effect of anterior and posterior repair on voiding.

We appreciate this comment; however, this was an exploratory, post-hoc analysis and after good suggestions by the reviewers, it would be inappropriate to include this in the manuscript as it was not a pre-specified analysis. The primary reviewer has also commented that “this analysis can't really be done in an RCT because any other characteristics associated with failing a voiding trial should have randomized out in the two groups”—we agree that, in theory, proper randomization in a RCT is expected to balance treatment groups with respect to patient characteristics and covariate levels on average, and while it is not unusual to observe imbalances post hoc, these imbalances or differences between arms may be attributable to a type I error or a random phenomenon. We have therefore decided to remove all reference to this post-hoc analysis. The manuscript has been appropriately revised.

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11. Line 145: Prescribed antibiotics for UTI prophylaxis was based on surgeon discretion with some providing daily antibiotic prophylaxis while catheter in situ, some prescribing a treatment course after catheter removed indefinitely, and some not providing any antibiotics unless symptomatic.

12. One of the secondary outcomes was UTI - more details concerning a comparison of patients receiving or not receiving antibiotics who went on to develop a UTI would be useful.

We appreciate this critique. We agree that data regarding antibiotic use, tracking those given antibiotics, and those who subsequently were treated for UTI at a later time would have been useful. Evaluating antibiotic prescribing practices in catheterized patients and the subsequent risk of UTI is a clinically useful question. Unfortunately, we did not collect data on antibiotic use or the length of catheter use in those patients who were identified to have postoperative UTIs.

STATISTICAL EDITOR’S COMMENTS:

1. line 55-56: The conclusion should include the primary outcome, using the language of non-inferiority, which is how the hypothesis was stated and how the conclusion should be cited. The proportion discharged with a catheter is a numerical difference, no statistical comparison was provided (there would be NS difference). There was no power analysis to discern safety and it would be difficult to generalize safety findings from samples of these sizes.

Changes made accordingly.

2. lines 161-162: Need to justify choice of 10% as the non-inferiority margin.

The choice of 10% was based on clinical judgment. Based on clinical experience, in this patient population of interest, the rate of re-catheterization within 6 weeks is approximately 5%. The clinicians were willing to accept a 10% noninferiority margin. To our knowledge there is no known data or limited literature regarding postoperative catheter reinsertion rates to help direct acceptable limits of the noninferiority margin for this study. Therefore, this margin was decided based on the clinical experience of the authors which we believe adds to the literature on catheter use following urogynecologic surgery.

3. lines 198: How does this p value (< .01) relate to the conclusion? The margin is clearly non-inferior vs the margin of 10%.
The p-value is the p-value using the Farrington-Manning method. We agree that the confidence interval is sufficient to conclude non-inferiority. This has been appropriately revised as follows:

For the primary endpoint, there was no statistically significant difference between treatment groups with respect to the number of patients who passed the TOV and subsequently required recatheterization for VD; FOS was non-inferior to SVT with respect to recatheterization rates (FOS, 2.8% [2/71], vs SVT, 3.1% [2/64], difference, -0.31%; 95% CI: -0.09% to 0.88%; p<0.01).

4. lines 200: What is the meaning of p < 1.0? There is apparently no difference.

We wanted to provide the actual p-values for all results so the reader has the complete information (in cases where the p-value is non-significant at 0.07, the reader will have that information). However, in order to conform to the journal standards, we revised any occurrence of “p<1.0” to “p=ns”. All non-significant p-values, were changed accordingly to this style.

5. lines 205-206, 207-208: What is the meaning of p < 0.2 or p < 0.21? There is no statistical difference.

All non-significant p-values, were changed accordingly to p=ns.

6. line 211: How does p < 0.02 relate to Fig 3? And if there was no difference, then why is p < .02?

This was a typo, thank you for your careful review. The p-value was in fact p=0.2218. This has been revised accordingly to p=ns.

7. lines 212-216: There were too few cases of VT failure to test for 12 variables. Were the age and pain score unadjusted or adjusted ORs? Should state the index used for age (ie, was this per year). Also, was the OR of 1.43 per year of age?

Thank you for this thoughtful comment. The final model included only two significant factors, namely, age and pain score at TOV, resulting from screening the 12 potential factors. The units for age was per year and the units for pain score was per one point increase in pain score. We presented the adjusted ORs for every unit increase in age and in pain score, and also presented corresponding adjusted ORs for failure using a 10-year increase in age and a 3-point increase in pain score. The following statements were in lines 218 to 221:

“For every 10-year increase in age, the odds of a TOV failure increased (OR=2.63, 95% CI: 1.6-4.3). In addition, we predicted that for every 3-point increase in pain score, the odds of TOV failure also increased (OR=2.9, 95% CI: 1.6-5.5).”

However, please note that the logistic regression analysis was carried out as an exploratory post-hoc analysis (i.e. it was not a pre-specified analysis in the protocol and was not planned for in the design stage of the study). Therefore, this may be deemed as inappropriate to include in the manuscript. The primary reviewer questioned the inclusion of this analysis, indicating that in a randomized clinical trial, all characteristics should have balanced out. We agree with the reviewer that in theory, proper randomization in a RCT is expected to balance treatment groups with respect to patient characteristics and covariate levels on average, and while it is not unusual to observe imbalances post hoc, these imbalances or differences between arms may be attributable to a ‘type I’ error or a random phenomenon. We have therefore decided to remove all reference to this post-hoc analysis. The manuscript has been appropriately revised.

We are removing reference to this particular analysis throughout the manuscript. This conforms with the ICH guidelines on

We are addressing the questions regarding the logistic regression model, but note that all data from this analysis will be removed from the manuscript.

8. lines 222-225: Were the AUA-SS and UDI-6 scores normally distributed? If not, then should cite as median(IQR or range), not as mean± SD and the comparisons should use non-parametric testing.

We used the Kruskal-Wallis test to compare AUA-SS and UDI-6 scores for the comparisons and accordingly, the median, Q1 and Q3 should be provided instead of the mean and SD. Changes were made as appropriate.
9. lines 223, 225, 227, 229: Why were the p values formatted as p < non significant values?

Changes were made accordingly—all nonsignificant p-values were formatted as “p=ns”

10. Should clearly identify the primary outcome in Table of results and separate it from the secondary outcomes and cite the primary in terms of non-inferiority testing.

We did not present the primary outcome in any table. If this is necessary, we will be able to make changes as requested.

11. Table 1: Since this was a RCT, no need to statistically compare the baseline characteristics. However, it is unfortunate that the randomization did not include blocks of prolapse stage, since the cohorts differed in distribution of Stages of apical prolapse, which may complicate interpretation of results.

Thank you for this comment, we have removed the column of p-values in Table 1.

12. Table 3: Need to cite p value for first row entry, other than < 0.3, should be a value.

Thank you for this comment, we have made the appropriate change. The p-value for this comparison was 0.2978, which we rounded to 0.30

13. Fig 3: Should enter the “n” remaining in each cohort at appropriate intervals along the x-axis.

Figure 3 has been revised to include the number at risk in each cohort along the x-axis.

EDITORIAL OFFICE COMMENTS:

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

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

We OPT-IN

2. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. This statement must appear at the end of your Materials and Methods section. 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). Examples of statements can be found online at http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf.

All de-identified data and study documents will be available to share following publication of data for future meta-analysis purpose.

3. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available
4. 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 appendixes).

Please limit your introduction to 250 words and your Discussion to 750 words.

5. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with the following guidelines:

* All financial support of the study must be acknowledged. None to report
* 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. None to report
* 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 signature on the journal's author agreement form verifies that permission has been obtained from all named persons. No additional persons to report besides authors listed.
* 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). Updates made to manuscript.

6. 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. Significant edits made. Word count 336.

7. 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.

Edits made to limit number of acronyms.

8. 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. Changes made accordingly.

9. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit. Changes made accordingly.

10. Our readers are clinicians and a detailed review of the literature is not necessary. Please shorten the Discussion and focus on how your results affect or change actual patient care. Do not repeat the Results in the Discussion section.
I've made changes to the discussion. Do you think this comment still applies now that I made changes?

Edits have been made to align with this critique.

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.

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

*Figure 3 – Author needs to submit figure as a high-res (at least 300 DPI) image file (JPEG, EPS, TIFF)*

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).

Uploaded figure 3 jpeg file separately and did not include in manuscript

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.

Figures should be no smaller than the journal column size of 3 1/4 inches. Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce. Refer to the journal printer’s web site (http://cjs.CADMUS.com/da/index.asp) for more direction on digital art preparation.

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

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

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 Nov 01, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

In response to the EU General Data Protection Regulation (GDPR), you have the right to request that your personal information be removed from the database. If you would like your personal information to be removed from the database, please contact the publication office.

In compliance with data protection regulations, please contact the publication office if you would like to have your personal information removed from the database.
Hi, I updated the following:

LINE 217: Here and throughout the manuscript, please revise all p values so that they are extend no more than 3 places past the decimal (i.e. \( p < 0.0001 \) should be \( p < 0.001 \)).

Thanks
Marjorie
Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 3:

On Dec 20, 2018, at 3:23 PM, Daniel Mosier <dmosier@greenjournal.org> wrote:

Dear Dr. Pilkinton,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 3:
Please list each author’s name as first name, middle initial (or full middle name), last name, academic degrees (no more than two per person).

Please ask the following authors to respond to the authorship confirmation email we sent. We sent an email from em@greenjournal.org. The message contains a link that needs to be clicked on. We emailed the authors at the email addresses below— are these the correct addresses?

- Cristina Sison: [redacted]

3. LINE 37: We will use the “FOS” abbreviation when you use it as the group name. Otherwise, it will be spelled out. Same for “SVT.”

4. LINE 40: Are you saying “two out of three” or “two thirds”? Please be sure this is clear throughout the paper.

5. LINE 45: It’s best to spell this out.

6. LINE 47: Please be sure this is stated in the body of your paper. Statements and data that appear in the Abstract must also appear in the body text for consistency.

7. LINE 49: Table 2 says 87. Which is correct?

8. LINE 172: For articles submitted to O&G after July 1, 2018, we require a data sharing statement indicating what we’ve listed here. Your answers may be different from what I’ve listed here. If so, please edit the responses accordingly.

9. LINE 231: This can only be stated here if there is a significant difference compared to SVT—line 216 suggests p=ns. It is unwarranted to have this as a focus point throughout the Discussion. The authors themselves agree in Response #3 to Reviewer #2, but it needs to be reflected in the manuscript as such.

10. LINE 239: See comment above

11. LINE 243: Unclear whether this would be considered a real difference

12. LINE 252: Later in the same sentence this is presented in mL—please be consistent.

13. LINE 271: The authors do not mention the 3rd secondary outcome: change in symptom profile anywhere in Discussion.

14. LINE 290: See above comment

15. TABLE 2: Abstract says 88.

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on Friday, December 27th.

Sincerely,

-Daniel Mosier

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<18-1692R1 ms (12-20-18v2).docx>
Hi,

Aq1: not sure i understand. there is a box showing 15 exclusions which is correct. yes 1 of the 15 was lost to follow up but the box below it shows 71 in the primary analysis which is correct.

Aq2: no problem, thank you.

On Dec 19, 2018, at 11:48 AM, Stephanie Casway <SCasway@greenjournal.org> wrote:

Hi again Dr. Pilkinton,

Your figures and legend have been edited, and PDFs of the figures and legend are attached for your review. Please review the figures CAREFULLY for any mistakes. In addition, please see our queries below.

AQ1: In Figure 2, the n values in the final exclusion box (force of stream group) total 16. Are these values not mutually exclusive, or should another value be updated?

AQ2: Note that we have edited the P value from Figure 3 to 3 decimal places per journal style. If this is a concern, please let me know.

PLEASE NOTE: Any changes to the figures must be made now. Changes at later stages are expensive and time-consuming and may result in the delay of your article’s publication.

To avoid a delay, I would be grateful to receive a reply no later than Friday, 12/21. Thank you for your help.

Best wishes,

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