

# OBSTETRICS & GYNECOLOGY



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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)\*
- 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](mailto:obgyn@greenjournal.org).

**Date:** Dec 14, 2018  
**To:** "Lisa Chao"  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-18-2159

RE: Manuscript Number ONG-18-2159

Postoperative Bladder Filling after Outpatient Laparoscopic Hysterectomy: A Prospective, Randomized Controlled Trial

Dear Dr. Chao:

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 Jan 04, 2019, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1: Abstract -

**Objective:** Does backfilling of the bladder decrease the time to spontaneous void and time to discharge after outpatient laparoscopic hysterectomy?

**Methods -** singled blinded RCT, 200 cc NS used to backfill the bladder. Time to void, time in PACU, and incidence of urinary retention were all recorded

**Results -** 153 women were included in the study. Group A had 75 women who were backfilled and 181 minutes to spontaneous void and Group B had 78 women with 206 minutes to spontaneous void. Time to void was decreased by 25 minutes but there was no significant change in time to discharge or incidence of retention.

**Conclusions -** Bladder filling decreases time to void but there is no change in time to discharge.

**Introduction -** Same day D/C after l/s hysterectomy is increasing in popularity. Earlier removal of catheters has been shown to decrease time to first void and the urogynecologists have found that backfilling the bladder is better than awaiting spontaneous voids. The hypothesis is that backfilling will decrease time to void and time to discharge.

**Materials and Methods -** IRB obtained, registration with clinicaltrials.gov completed. TLH and supracervical hysterectomies were included with appropriate exclusions. Randomization was done by block of 4 with an envelope. Assessment of spontaneous voiding was done after 5 hours to prevent distention and catheter was replaced if bladder had > 200 cc after 5 hr with voiding trial in 3-4 days.

The primary aim was to see if time to void was shortened. Also evaluated was whether narcotics or IVF affect time to void. Secondary aim was time to discharge with 30 min difference in PACU felt to be significant.

**Results -** 162 randomized, 81 per group, 6 from A and 3 from B excluded from analysis. No differences between groups and 98.7% of procedures were TLH.

**Primary outcome -** time to void was decreased by 24.9 minutes in the backfilled group. IVF did not affect timing but narcotics given prior to void did affect time.

**Time to discharge** was not significant and difference in urinary retention was not significant.

**Secondary outcome -** ED visits, UTIs, readmissions were all similar between groups.

**Discussion -** Backfilling the bladder decreases time to first void but doesn't change time to discharge. There is no increase in retention, UTI, or complications in backfilled group.

Comments -

This is an appropriate question given that voiding does constitute a discharge criteria. It is without complications, and reasonable to investigate.

It is addressed in an acceptable manner with randomization as stated.

The issues that I would like addressed:

1. What is the discharge criteria that is holding up discharge. If the patients are voiding more quickly, what is holding up the discharge. The explanation that it is nursing doesn't answer this because that affects both groups. Are they having nausea? Not ambulatory? If they are delayed for other reasons, than this 25 minute difference is not clinically relevant.
2. What would be the cost savings per patient if discharge could be affected by 25-30 minutes?
3. The distribution of TLH vs supercervical hyst was equal between the groups but was there a difference in time to void between the 2 groups of post-operative patients?
4. With twice as many patients being removed from the A group, was there any difference in statistics or affect on results from this?
5. The study is a reasonable question but lacks clinical significance, so I would be curious to know why there is no change in time to discharge.

Reviewer #2: This is a randomized controlled trial comparing the impact of immediate post-op (in OR) backfill of the bladder to 200 cc versus post-op removal of the catheter on time to first void. It follows CONSORT guidelines and is well designed, executed, and written up. Their primary outcome, a difference in time to first void of 24.9 minutes, while statistically significant, does not seem to be clinically meaningful, especially as it does not lead to earlier discharge or differences in post-op retention, ED visits, etc. The authors present their data well and clearly explain their conclusions, without overstating their findings.

In this time of increased attention to ERAS and early discharge, this is an interesting and timely topic.

Below is a point-by-point critique

1. Suggest including in the title what the primary outcome is, for example: "postoperative bladder filling after outpatient laparoscopic hysterectomy and time to first void: a randomized, controlled trial".
2. Why was 200 cc chosen as the amount to backfill? This amount is much lower than commonly accepted amounts for maximum capacity (300-600 cc), or even strong desire to void (250-500).
3. Can you explain your high rates of urinary retention (6.7 and 12.8%)? Is there existing literature to compare your rates to?
4. On line 234 you state that greater than or equal to 30 minutes was chosen for your sample size calculation as it was considered clinically significant, but on line 330 you cite another study as the reason for choosing 30 minutes. Please clarify. Also, if you did choose 30 minutes, why is that clinically important?
5. What do you make of your primary outcome of a difference of 24.9 minutes to void, which is less than your predetermined clinically significant time of 30 minutes?
6. Tables 1 and 2 could be combined.

Reviewer #3: This manuscript deals with the concept of backfilling the bladder prior to pulling the foley at the end of surgery in MIGS cases utilizing a ERAS protocol at a single institution. The authors provided a randomized prospective study comparing this group to a matched group that just had the foley removed. It shows statistically significant reduction in time until first adequate void but no reduction in the time until discharge. They provide a good description as to limitations of the study that might explain the reason for no difference in the time until discharge finding.

The manuscript is well written with few grammatical errors. The tables are good along with flow diagrams showing enrollment and the voiding protocol. Statistical analysis is appropriate and the study is adequately powered. Was a 2 tailed test used with the p value? Please clarify.

One additional criteria I would encourage including (if the information is available) would be a comparison in the sizes of the foley catheters in each group as a larger foley diameter may result in more irritation. Consider adding the ERAS discharge criteria/checklist utilized in addition to the voiding trial as this would clarify your reference to the ERAS protocol and why some patients stayed overnight and had to be excluded from the study.

The CONSORT checklist is complete.

#### STATISTICAL EDITOR'S COMMENTS:

1. Abstract: Need to re-write to conform to template for RCTs. Specifically, need to cite the primary outcome, then the secondary ones and need to cite the basis for sample size estimations. Need to clearly demarcate the primary (time to discharge from PACU) from the secondary outcomes. On Clinicaltrials.gov website, the primary outcome is time to spontaneous void, the secondary outcome is time to discharge from PACU. On lines 233-236, the sample size (and clinically important) difference was set at  $\geq 30$  minutes, for the secondary outcome. However, there is no justification for sample sizes re: the primary outcome. Need to outline justification for sample size for primary outcome. If in fact, two hypotheses were being tested, then inference threshold of .025 should be used which would require larger samples.
2. lines 232-236: Need to provide estimate for the SD of the time reduction, in order to complete the criteria for calculation of sample size.
3. lines 268-271: This is statistically significant, but what difference was a priori set as being clinically significant? If  $\geq 30$  minutes, then the difference is not significant. If both time to 1st spontaneous void and time to discharge were being tested, then should use a stricter p-value, in which case the latter difference ( $p = .041$ ) becomes NS.
4. lines 278-281, 284-288: Difference is NS, but the counts of adverse outcomes is low and therefore underpowered to generalize that there is no difference.
5. Table 1: Since this was a RCT, there is no need to statistically compare baseline characteristics. Any difference is thought to be due to random chance.
6. Table 2: Were the distributions cited as mean $\pm$ SD each normally distributed? If not, then should cite as median(range or IQR) and test non-parametrically. Should round EBL, IVF, urine output to nearest whole mL. Should round p-value to nearest .01
7. Table 3: Same comment re: times and whether normally distributed and rounding of p-values to nearest .01

#### 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](http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf).
  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. Tables, figures, and supplemental digital content should be original. The use of borrowed material (eg, lengthy direct quotations, tables, figures, or videos) is discouraged, but should it be considered essential, written permission of the copyright holder must be obtained. Permission is also required for material that has been adapted or modified from another source. Both print and electronic (online) rights must be obtained from the holder of the copyright (often the publisher, not the author), and credit to the original source must be included in your manuscript. Many publishers now

have online systems for submitting permissions request; please consult the publisher directly for more information. In addition, you must list any material included in your submission that is not original or that you are not able to transfer copyright for in the space provided under I.B on the first page of the author agreement form.

5. 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>.

6. 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.

7. 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.

8. 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 Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

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

10. 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.

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

12. 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.

13. 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.

14. 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.

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

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

"Figure 1: Please confirm that this is original to the manuscript."

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.

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 Jan 04, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

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

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

December 25, 2018

Dear Editors of *Obstetrics & Gynecology*,

Thank you for your consideration of our revised manuscript (Number ONG-18-2159) "Postoperative Bladder Filling after Outpatient Laparoscopic Hysterectomy and Time to Discharge: A Randomized Controlled Trial." Please find our attached responses to the comments made by the reviewers and the editor below.

REVIEWER COMMENTS:

Reviewer #1 Comments -

This is an appropriate question given that voiding does constitute a discharge criteria. It is without complications, and reasonable to investigate.

It is addressed in an acceptable manner with randomization as stated.

The issues that I would like addressed:

1. What is the discharge criteria that is holding up discharge. If the patients are voiding more quickly, what is holding up the discharge. The explanation that it is nursing doesn't answer this because that affects both groups. Are they having nausea? Not ambulatory? If they are delayed for other reasons, than this 25 minute difference is not clinically relevant.

Response: From the results of our clinical trial, a successful spontaneous voiding trial is not what holds up discharge in our cohort after outpatient laparoscopic hysterectomy as there may be other contributors, (i.e. post-operative nausea, pain, reliable transportation), that can delay a patient's discharge. These factors are stated in the discussion section of the manuscript (lines 585-591). The clinical relevance of a 24.9 minute difference has been addressed in the discussion section (lines 591-593). The nursing staff's discomfort with the newly compressed timeline of same-day discharge could be the rate limiting step in time to discharge instead of time to void, thus our intervention did not decreased recovery room time despite improving time to first spontaneous void.

2. What would be the cost savings per patient if discharge could be affected by 25-30 minutes?

Response: Although determining the cost savings per patient if discharge could be affected by 25-30 minutes would be interesting and relevant, this was not the focus of our study as further cost analyses would need to be performed. Cost is very difficult to determine in this setting because it is hard to quantify nursing costs (as

nurses are often taking care of multiple patients at one time), ancillary services (i.e. meals, use of patient care technicians, etc.), and overhead. Also cost savings are realized when a greater number of patients can be managed by a specific service line (i.e. recovery room staff) without an increase in overhead or if faster discharge of patients from the recovery room results in being able to downsize staff in the recovery room without reducing the number of patients cared for. These “savings” are very hard to accurately quantify.

3. The distribution of TLH vs supracervical hyst was equal between the groups but was there a difference in time to void between the 2 groups of post-operative patients?

Response: Although the distribution of TLH vs supracervical hysterectomies was equal between the two groups, there was only one supracervical hysterectomy performed in each group. The time to void was 172 minutes from the one patient in group A (1/75), and time to void from group B (1/78) was 200 minutes which is consistent with the results of our outcome reported in Table 3. Due to the very low number of patients (1 per group) who had a supracervical hysterectomy, the difference is not significant and therefore not reported in our results. There have also been no published studies reporting any differences in voiding function after TLH vs. supracervical hysterectomies.

4. With twice as many patients being removed from the A group, was there any difference in statistics or affect on results from this?

Response: Once it was determined patients needed to be admitted overnight, these patients were immediately excluded because our primary and secondary outcomes were not recorded for these patients, as time to discharge was irrelevant. The PACU voiding protocol was not followed by PACU nursing and voiding times were not obtained and therefore results were not affected. The admissions were for issues unrelated to voiding or bladder function and therefore would not affect the final results.

5. The study is a reasonable question but lacks clinical significance, so I would be curious to know why there is no change in time to discharge.

Response: This is addressed in the discussion section, (lines 585-593). See response to Question #1.

#### Reviewer #2 Comments –

This is a randomized controlled trial comparing the impact of immediate post-op (in OR) backfill of the bladder to 200 cc versus post-op removal of the catheter on time to first void. It follows CONSORT guidelines and is well designed, executed, and written up. Their primary outcome, a difference in time to first void of 24.9 minutes, while statistically significant, does not seem to be clinically meaningful, especially as



it does not lead to earlier discharge or differences in post-op retention, ED visits, etc. The authors present their data well and clearly explain their conclusions, without overstating their findings.

In this time of increased attention to ERAS and early discharge, this is an interesting and timely topic.

Below is a point-by-point critique

1. Suggest including in the title what the primary outcome is, for example: "postoperative bladder filling after outpatient laparoscopic hysterectomy and time to first void: a randomized, controlled trial".

Response: This change has been incorporated. "Postoperative Bladder Filling after Outpatient Laparoscopic Hysterectomy and Time to Discharge: A Randomized Controlled Trial."

2. Why was 200 cc chosen as the amount to backfill? This amount is much lower than commonly accepted amounts for maximum capacity (300-600 cc), or even strong desire to void (250-500).

Response: 200 cc was chosen as the amount to backfill to prevent post-operative overdistension given that the patient will continue to naturally produce urine as they are in the recovery room awaking from anesthesia. A normal adult bladder capacity can range from 400-550 cc, with a normal desire to void at 300-400 cc (lines 287-292).

3. Can you explain your high rates of urinary retention (6.7 and 12.8%)? Is there existing literature to compare your rates to?

Response: Our rates of urinary retention are comparable to what is reported in literature. Reported rates of urinary retention after laparoscopic hysterectomy have varied in literature as a result of different diagnostic criteria used to define retention, the use of regional and general anesthesia, and variability of catheter use in the postoperative period (Smorgick et al. Risk factors for Postoperative Urinary Retention After Laparoscopic and Robotic Hysterectomy for Benign Indications. *Obstet Gynecol* 2012;120:581-6). Their reported rates of urinary retention were 7.3% after laparoscopic supracervical hysterectomy and 10.3% for robotic-assisted supracervical hysterectomy. The incidence of postoperative urinary retention in women undergoing laparoscopic hysterectomy in another study was 7% (Ghezzi et al. Immediate Foley removal after laparoscopic and vaginal hysterectomy: determinants of postoperative urinary retention. *J Minim Invasive Gynecol* 2007;14:706-11). Another factor which could have resulted in our rates of urinary retention is that patients had a Foley catheter placed after either 5 or 6 hours of inability to void and were discharged home at that point. In a non-study setting, these patients may have been given more time (greater than 6 hours) to try to void

spontaneously (thus resulting in lower rates of urinary retention).

4. On line 234 you state that greater than or equal to 30 minutes was chosen for your sample size calculation as it was considered clinically significant, but on line 330 you cite another study as the reason for choosing 30 minutes. Please clarify. Also, if you did choose 30 minutes, why is that clinically important?

Response: This has been corrected. The sample size was calculated based on prior study data.

5. What do you make of your primary outcome of a difference of 24.9 minutes to void, which is less than your predetermined clinically significant time of 30 minutes?

Response: Although our outcome showed a difference of 24.9 minutes to void, it was not clinically relevant as it did not show a difference in time to discharge.

6. Tables 1 and 2 could be combined.

Response: Changes to Tables 1 and 2 have been modified.

Reviewer #3: This manuscript deals with the concept of backfilling the bladder prior to pulling the foley at the end of surgery in MIGS cases utilizing a ERAS protocol at a single institution. The authors provided a randomized prospective study comparing this group to a matched group that just had the foley removed. It shows statistically significant reduction in time until first adequate void but no reduction in the time until discharge. They provide a good description as to limitations of the study that might explain the reason for no difference in the time until discharge finding.

The manuscript is well written with few grammatical errors. The tables are good along with flow diagrams showing enrollment and the voiding protocol. Statistical analysis is appropriate and the study is adequately powered. Was a 2 tailed test used with the p value? Please clarify.

Response: This change has been incorporated in the manuscript in the Materials and Methods section (lines 351-357).

One additional criteria I would encourage including (if the information is available) would be a comparison in the sizes of the foley catheters in each group as a larger foley diameter may result in more irritation. Consider adding the ERAS discharge criteria/checklist utilized in addition to the voiding trial as this would clarify your reference to the ERAS protocol and why some patients stayed overnight and had to be excluded from the study.

Response: Discharge criteria has been added to the manuscript (lines 309-313). Patients in both groups had the same size Foley catheter used. Our standard protocol is to use a 16F Foley catheter for all gynecologic laparoscopy cases unless there is an

issues (inability to insert the catheter, urethral stricture, etc). There were no cases in this study that needed a different size catheter.

The CONSORT checklist is complete.

#### STATISTICAL EDITOR'S COMMENTS:

1. Abstract: Need to re-write to conform to template for RCTs. Specifically, need to cite the primary outcome, then the secondary ones and need to cite the basis for sample size estimations. Need to clearly demarcate the primary (time to discharge from PACU) from the secondary outcomes. On Clinicaltrials.gov website, the primary outcome is time to spontaneous void, the secondary outcome is time to discharge from PACU. On lines 233-236, the sample size (and clinically important) difference was set at  $\geq 30$  minutes, for the secondary outcome. However, there is no justification for sample sizes re: the primary outcome. Need to outline justification for sample size for primary outcome. If in fact, two hypotheses were being tested, then inference threshold of .025 should be used which would require larger samples.

Response: These changes have been incorporated into the manuscript. Our primary outcome was looking at time to discharge or length of time spent in the PACU as our study was powered accordingly and this has been clarified both in the revision of this manuscript and on clinicaltrials.gov.

2. lines 232-236: Need to provide estimate for the SD of the time reduction, in order to complete the criteria for calculation of sample size.

Response: This change has been added to lines 355-357.

3. lines 268-271: This is statistically significant, but what difference was a priori set as being clinically significant? If  $\geq 30$  minutes, then the difference is not significant. If both time to 1st spontaneous void and time to discharge were being tested, then should use a stricter p-value, in which case the latter difference ( $p = .041$ ) becomes NS.

Response: The authors agree – the result in question is statistically significant, however, not clinically significant and this change has been reflected in our manuscript.

4. lines 278-281, 284-288: Difference is NS, but the counts of adverse outcomes is low and therefore underpowered to generalize that there is no difference.

Response: These changes have been made in the manuscript (lines 465-468).

5. Table 1: Since this was a RCT, there is no need to statistically compare baseline

characteristics. Any difference is thought to be due to random chance.

Response: These changes have been made and are reflected in Table 1.

6. Table 2: Were the distributions cited as mean $\pm$ SD each normally distributed? If not, then should cite as median(range or IQR) and test non-parametrically. Should round EBL, IVF, urine output to nearest whole mL. Should round p-value to nearest .01

Response: These changes have been incorporated in the revised manuscript.

7. Table 3: Same comment re: times and whether normally distributed and rounding of p-values to nearest .01

Response: These changes have been incorporated in the revised manuscript.

#### 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.

Response: OPT-IN: Yes, please 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](http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf).

Response: The data sharing statement has been added to the end of the Materials and Methods section of the manuscript in lines 365-366.

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.

Response: This statement has been included in the original cover letter as well as at the end of this version of the cover letter.

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

5. 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>.

6. 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.

Response: The Introduction has been modified to 248 words and Discussion to 747 words. This manuscript does not exceed 22 typed pages, double-spaced.

7. 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.

Response: The title has been modified to meet the character limit as follows: "Postoperative Bladder Filling after Outpatient Laparoscopic Hysterectomy and Time to Discharge" and the subtitle "A Randomized Controlled Trial" has been added.

8. 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 Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

Response: In our acknowledgement on the title page, "The project described was supported by the National Institutes of Health through Grant Number UL1TR001857" This supported the data/statistical analysis, which was provided by the Clinical and Translational Science Institute of the University of Pittsburgh. This has been revised on the title page.

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

Response: "Bladder Testing after Laparoscopic Hysterectomy" (43 characters) has been added as a running foot.

10. 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.

Response: The abstract has been revised and the word count is 296 words.

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

Response: The abstract has been revised.

12. 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.

Response: These changes have been noted throughout the manuscript.

13. 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.

Response: These changes have been made throughout the manuscript.

14. 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.

Response: These changes have been made in the discussion and the repeated results have been revised.

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

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

"Figure 1: Please confirm that this is original to the manuscript."

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.

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.

Response: The statistical output have been attached as a supplement.

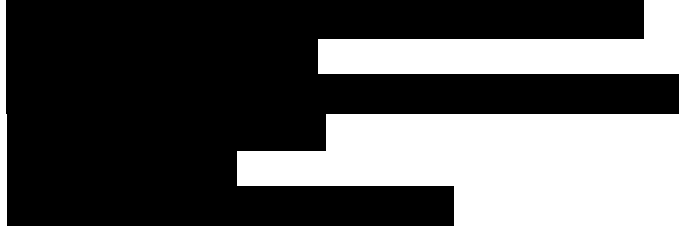
Author Declaration of Transparency:

I, Dr. Lisa Chao, 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.



Sincerely,

Lisa Chao, M.D.



## Daniel Mosier

---

**From:** Lisa Chao [REDACTED]  
**Sent:** Friday, January 25, 2019 3:15 PM  
**To:** Daniel Mosier  
**Subject:** Re: Manuscript Revisions: ONG-18-2159R1

Hi Daniel,

Thank you for the revisions. I have read through the manuscript and do not disagree with any of these changes. However, there are two corrections I would like to make to the manuscript.

1.  
LINE 70: "postoperative complications within 4 weeks" should be "postoperative complications within **8** weeks"  
LINE 382: "Despite being a feasible with no" should be "Despite being feasible with no" (grammatical error after revision of the sentence)

2.  
The two supplemental digital content files are not intended for publication. I had thought the editors wanted the statistical output which was why I included them with my revision. Please disregard.

3. I have reviewed the data sharing statement and it looks accurate.

4. LINE 250: I agree with this deletion.

Thank you and please let me know if there are any further questions.

Best,  
Lisa

Lisa Chao, MD  
Assistant Professor of Obstetrics & Gynecology  
University of Texas Southwestern Medical Center  
[REDACTED]

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**From:** Daniel Mosier <dmosier@greenjournal.org>  
**Sent:** Friday, January 25, 2019 1:12 PM  
**To:** Lisa Chao  
**Subject:** Manuscript Revisions: ONG-18-2159R1

Dear Dr. Chao,  
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 16: We received two supplemental digital content files with your revised manuscript. Are these intended for publication? If so, please cite them in the manuscript as Appendix 1 and Appendix 2.
3. LINE 240: Please review the responses to the questions here and edit if needed.
4. LINE 250: Do not need this level of detail

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 **Tuesday, January 29th**.

Sincerely,

-Daniel Mosier

**Daniel Mosier**

Editorial Assistant

*Obstetrics & Gynecology*

The American College of Obstetricians and Gynecologists

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**UT Southwestern**

Medical Center

The future of medicine, today.

**From:** [REDACTED]  
**To:** [Stephanie Casway](#)  
**Subject:** Re: O&G Figure Revision: 18-2159  
**Date:** Wednesday, January 23, 2019 6:32:19 PM

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Hi Stephanie,

Both figures and the legend all look good!

Thanks,  
Lisa

Lisa Chao, MD

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

---

**From:** Stephanie Casway <SCasway@greenjournal.org>  
**Sent:** Wednesday, January 23, 2019 1:23 PM  
**To:** Lisa Chao  
**Subject:** O&G Figure Revision: 18-2159

Good Afternoon Dr. Chao,

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.

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, 1/25. Thank you for your help.

Best wishes,

Stephanie Casway, MA  
Senior Production Editor  
*Obstetrics & Gynecology*  
American College of Obstetricians and Gynecologists  
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