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)*

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

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Date: Jul 31, 2020
To: "Olga Anna Edith Wihersaari" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-1807

RE: Manuscript Number ONG-20-1807

Complications of pelvic organ prolapse surgery in Finland- FINPOP 2015 Study

Dear Dr. Wihersaari:

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).

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

REVIEWER COMMENTS:

Reviewer #1:

Title: Complications of pelvic organ prolapse surgery in Finland- FINPOP 2015 Study
General Comments: This is a large cohort study of women undergoing surgical repair of prolapse in a Finnish population. The investigators followed women one year after their surgery and recorded major complications according to the Dindo scale. The cohort is large and the methods robust to collect complications. The authors conclude that complications are relatively rare and that abdominal mesh procedures have higher complications as compared to native tissue and transvaginal mesh repairs. Specific comments are below:

1. The use of so many abbreviations in the abstract is distracting and difficult to follow.

2. The first statement of the introduction should have a disclaimer that this refers to POP on exam.

3. Did the authors have a hypothesis when they designed this study? Please include one in the introduction.

4. The introduction is a bit long and could be made more brief.

5. Line 101: "This included each of 5 university hospitals, 15 primary hospitals, 17 secondary hospitals and 5 private clinics". Please explain the differences between primary and secondary hospitals as well as how these surgeries could have been performed in a private clinic. Are the private clinics outpatient surgery centers?

6. I could not find the Mattesson 2019 reference to understand the surgical approaches. Please include a brief description in this publication for the readers. If the surgeries were all open abdominal surgeries, then the higher perioperative complications would not be as relevant to surgeries done, for example in the US, where most of these cases are done minimally invasively.

7. Please define the route of abdominal mesh - were these open or closed procedures as it is known that the rate of complications is greater in the open procedures.

8. Line 111: Data are plural - please make this correction throughout

9. Line 147: "Therefore, in case of multiple adverse events occurring to one patient, each adverse event was graded separately" This needs to be explained further as it has direct implications on the rates of adverse events. If there were a

series of problems in one day on a single patient, would this be considered as multiple adverse events?

10. The number of native tissue repairs far outweigh the number of transvaginal mesh and abdominal mesh repairs. Were the transvaginal mesh and the abdominal mesh repairs performed at fewer sites than the native tissue repairs? Were these surgeons somehow different than the surgeons who performed the native tissue repairs? This is important since it may bias results.

11. I think that the discussion should include a statement that this does not take into account that abdominal mesh repairs are generally have a higher success rate than native tissue repairs, and that in the long term some of the failures of native tissue and need for reoperation for prolapse may outweigh the advantage of fewer complications.

Reviewer #2: ONG-20-1807

This is a prospective cohort study done in Finland to evaluate the rate of 12 months complication rate in women undergoing vaginal repair compared to Vaginal mesh and abdominal mesh repair!

Main issues:
1- What is the new information provided by this study compared to prior literature!

2- It is important to differentiate vaginal repairs with and without apical suspension, as isolated anterior and posterior wall repair with not apical support procedure is not the best approach and while not associated with intraoperative complications, it is associated with higher failure rate!

Specific issues:
1- Introduction: can be shorter

2- Methods:
a. Please include the study type as prospective cohort study!
b. Evaluation of surgical difficulty after the surgery can result in
c. Please add specific definition of severe complication based on Dido classification!

3- Results:
a. Please include the number of patients who refused participation in the study and those who were excluded and please include those in a flow chart!
b. How much laparoscopic and robotic surgeries done among those abdominal mesh procedures?
c. What was the rate of vaginal apical suspension e.g. uterosacral colpopexy and sacrospinous apical suspension in this study?
d. Line 204: "coronary stroke" do you mean coronary artery disease?
e. Please provide info of complication rates in each of the subgroups of apical suspension surgeries both the overall and for each of the Dindo categories

4- Discussion:
a. Line 243: Please reconsider the use of "Low rate" of complications of 11.2%!
b. Please add how the results of this study affect the care of the next patient who is interested in POP surgery?

Reviewer #3:
Thanks for inviting me to review this interesting paper about complications associated with pelvic organ prolapse (POP) surgery in Finland.

The paper describes a prospective cohort of 3535 POP surgeries (native tissue repairs (NTR) n=2855; transvaginal mesh (TVM) n=429; abdominal mesh (AM) n=251), representing 83% of all POP surgeries carried out in Finland in 2015. Patients were followed up for one year after surgery. Data were collected on perioperative, postoperative and late complications of surgery. 11.2% of women had at least one complication, most commonly within 2 months of surgery. NTR had the lowest rates of bladder and bowel injuries and complications. Mesh surgery, longer operating time, prior POP surgery and difficult surgery were associated with increased risk of major complication, however serious adverse events were rare.

The research was rigorously designed and carried out by a well-known group of researchers and including a new investigator. The group has previously published several papers presenting analyses related to this research, however the comparison of complications associated with different methods of POP surgery is new to my knowledge.

This paper is clearly written.
The background explains the rationale for the research.
The methods are described in detail providing all definitions as required. Data handling and analysis are presented clearly.
The results are presented in detail, with each step of the analysis described, with supplementary analysis details provided in supplementary tables.
The discussion is long and detailed.

This is an unusually complete description of a straightforward study. The paper length could be reduced a little by transferring Tables 1 and 2 to the appendices. These tables are already available in a paper by Mattisson et al 2019.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

lines 46-48: Need to cite pairwise stats test to support that one group had significantly higher rate. The comparison of all 3 groups merely tests whether the variation is due to random chance, not that one particular group was "highest", that may be true nominally, but needs statistical proof. In Abstract, should cite the count within each surgical cohort, not just the overall total.

lines 225-240 and Table 5: The stats tests used (chi-square or Fisher's) do not allow identification of one of the three cohorts as being significantly different, but rather tests whether the distribution of adverse outcomes among the 3 cohorts is random. Need to support statements with pair-wise tests or modify the statements.

Table 6: Should round all ORs, aORs and their CIs to nearest 0.01, not to 0.001 precision. Since CIs are given, no need to include p-values. Could embolden the associations that were statistically significant. The groups TV or abd Mesh have relatively fewer patients, with lower absolute counts of adverse outcomes and thus may represent over fitted models.

EDITOR COMMENTS:

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

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained."
*The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

4. Please submit a completed STROBE checklist and a completed RECORD checklist.

Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

5. Your study uses ICD-10 data, please make sure you do the following:
a. State which ICD-10-CM/PCS codes or algorithms were used as Supplemental Digital Content.
b. Use both the diagnosis and procedure codes.
c. Verify the selected codes apply for all years of the study.
d. Conduct sensitivity analyses using definitions based on alternative codes.
e. For studies incorporating both ICD-9 and ICD-10-CM/PCS codes, the Discussion section should acknowledge there may be disruptions in observed rates related to the coding transition and that coding errors could contribute to limitations of the study. The limitations section should include the implications of using data not created or collected to answer a specific research question, including possible unmeasured confounding, misclassification bias, missing data, and changing participant eligibility over time.
f. The journal does not require that the title include the name of the database, geographic region or dates, or use of database linkage, but this data should be included in the abstract.
g. Include RECORD items 6.3 and 7.1, which relate to transparency about which codes, validation method, and linkage were used to identify participants and variables collected.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

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

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

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

revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

10. 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.

11. Line 274 and elsewhere: 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.

12. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

12. 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.

13. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

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

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter.

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

Again, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by Aug 30, 2020, we will assume you wish to withdraw the manuscript from further consideration..

Sincerely,

John O. Schorge, MD
Associate Editor, Gynecology

2019 IMPACT FACTOR: 5.524
2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

Submission of revised manuscript ONG-20-1807, “Complications of pelvic organ prolapse surgery in Finland- FINPOP 2015 Study”

John O. Schorge, MD
Associate Editor, Gynecology
The Editorial board of Obstetrics & Gynecology
409 12th Street SW
Washington, DC 20024
Tel: 202-314-2317
E-mail: obgyn@greenjournal.org

August 18th, 2020

Dear Editor,

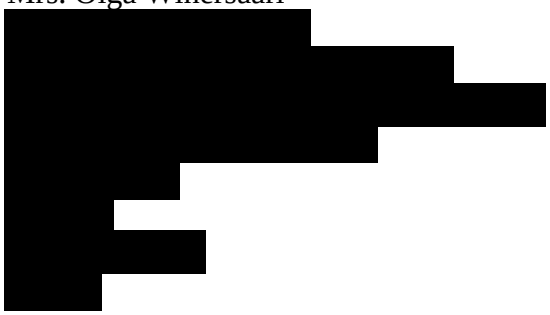
We are pleased to submit our revision of manuscript ONG-20-1807 entitled " Complications of pelvic organ prolapse surgery in Finland- FINPOP 2015 Study ". We thank for the positive review and insightful comments. Below we provide point-to-point description of the changes made to the manuscript. We confirm to have read and followed the Instructions for Authors when conducting the manuscript revision.

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.

We hope that our revised manuscript will be accepted in Obstetrics & Gynecology.

Yours Sincerely,

Mrs. Olga Wihersaari



August 18th, 2020

Manuscript: ONG-20-1807
Title: Complications of pelvic organ prolapse surgery in Finland- FINPOP 2015 Study

Author's responses to reviewer comments (Reviewers' comments have been reproduced and numbered; authors' responses are printed as intended).

Comment from the Associate Editor:

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.

> **Authors' response to the Associate Editor:** We appreciate this thorough review and have now revised the manuscript according to Reviewers comments. Please find the point by point answers to Reviewers' comments below.

Reviewer #1 (Comments to the Author):

Title: Complications of pelvic organ prolapse surgery in Finland- FINPOP 2015 Study

General Comments: This is a large cohort study of women undergoing surgical repair of prolapse in a Finnish population. The investigators followed women one year after their surgery and recorded major complications according to the Dindo scale. The cohort is large and the methods robust to collect complications. The authors conclude that complications are relatively rare and that abdominal mesh procedures have higher complications as compared to native tissue and transvaginal mesh repairs.

Specific comments are below:

1. The use of so many abbreviations in the abstract is distracting and difficult to follow.

> **Author's response:** We thank the reviewer for this valuable comment. The use of abbreviations has been reduced in order to make the abstract easier to follow.

2. The first statement of the introduction should have a disclaimer that this refers to POP on exam.

> **Author's response:** We thank the reviewer for this suggestion. The first statement of the introduction, which previously stated "Pelvic organ prolapse (POP) is a common condition affecting up to 50% of parous women", has been changed as follows: "Pelvic organ prolapse (POP) is a common and often asymptomatic condition, affecting up to 50% of parous women when based on examination."

3. Did the authors have a hypothesis when they designed this study? Please include one in the introduction.

Author's response: We thank for the opportunity to clarify this point. The study was designed to identify the differences in occurrence of major complications between the three surgical groups in this nationwide cohort. We were especially curious about the occurrence of mesh related complications and whether these surgeries are associated with higher rates of major complications compared to native tissue surgery. We did not prepare any specific hypothesis for the outcome since we wished to approach the subject open-mindedly. The aims of the study were stated in the originally submitted manuscript as follows (lines 89-93): "The aim of this prospective study was to describe the complications related to pelvic organ prolapse surgery in a population-based cohort including 83% of POP surgeries performed in Finland during 2015. We did this separately for native tissue and mesh augmented surgery. We also aimed to identify predictors for major adverse events."

In order to make the aims more comprehensible we have revised the last two sentences of the introduction as follows: "The aim of this prospective study was to describe the complications related to pelvic organ prolapse surgery in a population-based cohort including 83% of POP surgeries performed in Finland during 2015. We studied whether the risk of major complications was different by type of surgery and aimed to identify predictors for major adverse events."

4. The introduction is a bit long and could be made more brief.

Author's response: We appreciate this suggestion. The introduction has been made more compact.

5. Line 101: "This included each of 5 university hospitals, 15 primary hospitals, 17 secondary hospitals and 5 private clinics". Please explain the differences between primary and secondary hospitals as well as how these surgeries could have been performed in a private clinic. Are the private clinics outpatient surgery centers?

Author's response: We apologize for the lack of information and inconsistency. Each participating hospital provides similar surgical treatment and care, meeting the national standard requirements of Finnish National Supervisory Authority for Welfare and Health (VALVIRA). The hospitals differ mainly in size and location and therefore we have altered the description of hospital names as follows: "primary" to "central", "secondary" to "regional" and "private clinic" to "private hospital". Line 101 has been revised as follows: "This included each of 5 university hospitals, 15 central hospitals, 17 regional hospitals and 5 private hospitals".

The private clinics are inpatient centers providing overnight medical care postoperatively, similarly to all other hospitals participating in this study.

6. I could not find the Mattesson 2019 reference to understand the surgical approaches. Please include a brief description in this publication for the readers. If the surgeries were all open abdominal surgeries, then the higher perioperative complications would not be as relevant to surgeries done, for example in the US, where most of these cases are done minimally invasively.

Author's response: We thank the reviewer for this valuable comment. Out of all AM surgeries 91.0% were performed by laparoscopy, i.e. majority of these procedures were minimally invasive. In order to clarify this in the manuscript, we have added the information to the "results"-section of the manuscript, line: "Majority (91.0%) of AM surgeries were laparoscopic."

The methods of surgery for this cohort have been thoroughly described by Mattsson et al in Acta Obstetricia et Gynecologica Scandinavica 2019. A free access to the publication is available at:

https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/aogs.13520.

7. Please define the route of abdominal mesh - were these open or closed procedures as it is known that the rate of complications is greater in the open procedures.

Author's response: As mentioned in previous response to Q6, majority (91.0%) of abdominal surgeries were minimally invasive. We have now revised the manuscript and added a mention of the count of laparoscopic surgeries to the Results as follows: "Majority (91.0%) of AM surgeries were laparoscopic."

8. Line 111: Data are plural - please make this correction throughout

Author's response: We apologize for this typo. We have now revised the manuscript and corrected the suggested error throughout.

9. Line 147: "Therefore, in case of multiple adverse events occurring to one patient, each adverse event was graded separately" This needs to be explained further as it has direct implications on the rates of adverse events. If there were a series of problems in one day on a single patient, would this be considered as multiple adverse events?

Author's response:

We thank the reviewer for this valuable comment. As stated in the methods, each adverse event was graded separately. The grading of adverse events according to Clavien Dindo- grading system is explained further in the results (lines 226-228), describing the occurrence of major adverse events (CD grade 3-5) within each surgical group: "We observed one major complication in 97 patients (63 in NTR, 18 in TVM and 16 in AM group), two in 19 patients (11 in NTR, 3 in TVM and 5 in AM group) and three in 2 patients (1 NTR and 1 in AM group)." Thus, if there were a series of problems in one day on a single patient, they were considered as multiple adverse events.

10. The number of native tissue repairs far outweigh the number of transvaginal mesh and abdominal mesh repairs. Were the transvaginal mesh and the abdominal mesh repairs performed at fewer sites than the native tissue repairs? Were these surgeons somehow different than the surgeons who performed the native tissue repairs? This is important since it may bias results.

Author's response: We appreciate the query. As mentioned in our response to Q6, a thorough description of methods of surgery in this cohort is available in the publication by Mattsson et al (2019). Health district area and hospital type were factors, which were

associated with the use of mesh, as reported in Table 3 by Mattsson et al. However, all three surgical types presented in this study were performed in each participating hospital.

The native tissue surgeries in this study were performed by either specialists or supervised gynecology trainees. Mesh surgeries, however, were only performed by specialists.

11. I think that the discussion should include a statement that this does not take into account that abdominal mesh repairs are generally have a higher success rate than native tissue repairs, and that in the long term some of the failures of native tissue and need for reoperation for prolapse may outweigh the advantage of fewer complications.

Author's response: We thank the reviewer for this valuable comment. We have altered the concluding paragraph of the discussion (lines 321-328), which previously stated: "The results of this Finnish national cohort study show that POP surgery is a relatively safe procedure associated with a low rate of serious complications. However, the higher risk of serious adverse events and surgical complications, such as bowel and bladder injuries associated with mesh procedures should be considered and discussed with the patient when planning POP surgery. AM surgery was associated with higher risk of major complications than TVM, which should be taken into consideration when dealing with multimorbid elderly patients. Unlike previous studies, multiple compartment repair did not raise the risk for complications. In further studies, longer follow-up period will show whether further risk factors, especially associated with mesh complications, will appear"

The revised version states: "The results of this Finnish national cohort study show that POP surgery is a relatively safe procedure associated with a low rate of serious complications. The main priority of POP surgery should be in improving the woman's quality of life by reducing the symptoms and providing the best possible anatomic durability with minimal risks. Even though long term success rates of AM procedures are quite promising, the higher risk of serious adverse events and surgical complications, such as bowel and bladder injuries associated with mesh procedures should be carefully considered and discussed with the patient when planning POP surgery. AM surgery was associated with higher risk of major complications than TVM, which should be taken into consideration when dealing with multimorbid elderly patients. Unlike previous studies, multiple compartment repair did not raise the risk for complications. In further studies, longer follow-up period will show whether further risk factors, especially associated with mesh complications, will appear."

Reviewer #2 (Comments to the author):

This is a prospective cohort study done in Finland to evaluate the rate of 12 months complication rate in women undergoing vaginal repair compared to Vaginal mesh and abdominal mesh repair!

Main issues:

1. What is the new information provided by this study compared to prior literature!

Author's response: We appreciate the query. As mentioned in the discussion, only a few previous studies have provided comparison of POP surgery complications between native tissue repair and both transvaginal- and abdominal mesh surgeries. The study population size, follow-up time and the extensive data on major adverse events related to POP surgery provide valuable information of the differences of these three surgical groups. Additionally, there is no prior publication of POP surgery complications in Finnish population in this extent.

2. It is important to differentiate vaginal repairs with and without apical suspension, as isolated anterior and posterior wall repair with not apical support procedure is not the best approach and while not associated with intraoperative complications, it is associated with higher failure rate!

Author's response: We thank the reviewer for this important comment. The main focus of this study was to report serious adverse events of POP surgery in the three surgical groups. Multiple compartment repair was included in the analysis of possible risk factors for the occurrence of major adverse events. Our results (uni- and multivariable models represented in table 6 and appendix 1) show that multiple compartment repair did not increase the risk for major complications.

The methods of surgery for this cohort have been thoroughly described by Mattsson et al in Acta Obstetricia et Gynecologica Scandinavica 2019 (free access to the publication is available at https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/aogs.13520). As described in this publication, majority (67.3%) of TVM procedures were multiple compartment repairs. 23.5% of surgeries were performed to anterior vaginal wall only, 2.8% to apex only and 6.3% to posterior vaginal wall only.

The long-term results of each three surgical approaches is not yet available for FINPOP study. However, we hope that the study's 5-year follow up data of reoperations will shed light on this matter.

Specific issues:

1. Introduction: can be shorter

Author's response: We appreciate this suggestion. We have shortened the introduction as requested.

2. Methods:

a. Please include the study type as prospective cohort study!

Author's response: We apologize for this flaw. Although this is mentioned in the abstract, the mention of study type was not included in the methods. We have now revised the manuscript with the addition of study type in the methods as well.

b. Evaluation of surgical difficulty after the surgery can result in

Author's response: (Note: The question was left unfinished by the reviewer). We thank the reviewer for pointing this out. We acknowledge that the assessment of surgical difficulty after surgery was a subjective evaluation. Although the association between difficult surgery and the occurrence of major complication was quite interesting, we attempted not to emphasize this result in the manuscript.

c. Please add specific definition of severe complication based on Dido classification!

Author's response: We thank the reviewer for this comment. The definition of major/severe complication according to Clavien Dindo classification is stated in the methods as follows (lines 141-143): "Clavien Dindo (CD) classification was used to grade major complications (CD grades 3a-5): complications requiring surgical intervention under local (3a) and general (3b) anesthesia, single organ (4a) and multi organ (4b) dysfunction and death of patient (5)." Additionally, the complete descriptions of each subgrade are provided in the footnotes of table 5 (line 428): "Grade 3 adverse events are defined as requiring surgical, endoscopic or radiological intervention under local anesthesia (3A) and general anesthesia (3B). Grade 4 as life-threatening complication (including CNS complications) requiring IC/ICU management, with either single organ dysfunction (including dialysis) (4A) or multi-organ dysfunction (4B). Grade 5 event as death of patient."

3. Results:

a. Please include the number of patients who refused participation in the study and those who were excluded and please include those in a flow chart!

Author's response: We appreciate the reviewer's suggestion. 4240 POP surgeries were performed in Finland between January 1st 2015 and December 31st 2015. As mentioned in the methods, this study includes 83% of these surgeries. A flow diagram of study enrollment has been previously published by Mattsson et al 2019, but a flow chart of participation and amount of complications in each surgical group has been added to the revised manuscript as requested. Altogether 705 women did not participate in the study for unknown reasons. Of those women who participated in this study, however, a thorough collection of complication data within one year after surgery was performed. That is to say, none were lost to follow-up since complication data was collected from multiple sources.

b. How much laparoscopic and robotic surgeries done among those abdominal mesh procedures?

Author's response: We appreciate the query. As mentioned in the response to "Main issues" Q2, Mattsson et al (2019) have previously described the methods of surgery in this cohort. 91% of abdominal mesh surgeries were performed by laparoscopy. There were no robotic surgeries in this study.

c. What was the rate of vaginal apical suspension e.g. uterosacral colpopexy and sacrospinous apical suspension in this study?

Author's response: We thank the reviewer for this comment. The rates of individual surgical approaches are thoroughly described in the publication by Mattsson et al (2019), more specifically in Appendix 1. The count of sacrospinosus fixation was 46 (39 of which were combined with colporraphy) and the count of hysteropexy was 5 (4 of which were combined with colporraphy).

d. Line 204: "coronary stroke" do you mean coronary artery disease?

Author's response: We thank the reviewer for this comment. In our manuscript we have referred to sudden heart attack due to coronary artery disease as "coronary stroke". However, to avoid confusion we have altered this to "acute myocardial infarction (AMI)".

e. Please provide info of complication rates in each of the subgroups of apical suspension surgeries both the overall and for each of the Dindo categories

Author's response: We thank the reviewer for this request. The rates of apical suspension surgeries in each of the subgroups have been previously published by Mattsson et al (2019). The rate of single compartment repairs to apex only were the highest in AM group (30.4%) and lowest in TVM group (2.8%). Overall 60.9% of women in this study had POP surgery with apical repair. The aims of this study were to describe the complications associated with the three different surgical approaches and to evaluate possible risk factors associated with complications related to prolapse surgery. Our opinion is that answering this question thoroughly would require a separate study with a somewhat different kind of study setting, with more close comparison of surgical approaches and similar in-between-groups baseline characteristics.

4. Discussion:

a. Line 243: Please reconsider the use of "Low rate" of complications of 11.2%!

Author's response: We thank you for this valuable comment. The referred line in our manuscript states: "Low rates of individual surgical and non-surgical complications were observed, with an average complication rate of 11.2%." When using the term "low rate" we refer to individual surgical and non-surgical complications, which are shown in tables 3 and 4. The rate of individual non-surgical complications was less than 1% and the rate of individual surgical complications 0-5.6%, respectfully. In order to avoid misinterpretation, we have revised the line as follows: "Low rates of individual surgical and non-surgical complications were observed, with a moderate overall complication rate of 11.2%."

b. Please add how the results of this study affect the care of the next patient who is interested in POP surgery?

Author's response: We appreciate the query. As already stated in the concluding paragraph of the discussion, "the higher risk of serious adverse events and surgical complications, such as bowel and bladder injuries associated with mesh procedures should be carefully considered and discussed with the patient when planning POP surgery. AM surgery was associated with higher risk of major complications than TVM, which should be taken into consideration when dealing with multimorbid elderly patients."

Only a few previous studies have provided comparison of POP surgery complications between native tissue repair and both transvaginal- and abdominal mesh surgeries. The study population size, follow-up time and the extensive data on major adverse events related to POP surgery provide valuable information of the differences of these three surgical groups. When treating POP patients, the most suitable operative approach should be selected, taking into account each individual patient's health status, prolapse stage, severity of symptoms and the patient's expectations regarding the surgical treatment.

Reviewer #3 (Comments to the author):

Thanks for inviting me to review this interesting paper about complications associated with pelvic organ prolapse (POP) surgery in Finland.

The paper describes a prospective cohort of 3535 POP surgeries (native tissue repairs (NTR) n=2855; transvaginal mesh (TVM) n=429; abdominal mesh (AM) n=251), representing 83% of all POP surgeries carried out in Finland in 2015. Patients were followed up for one year after surgery. Data were collected on perioperative, postoperative and late complications of surgery. 11.2% of women had at least one complication, most commonly within 2 months of surgery. NTR had the lowest rates of bladder and bowel injuries and complications. Mesh surgery, longer operating time, prior POP surgery and difficult surgery were associated with increased risk of major complication, however serious adverse events were rare.

The research was rigorously designed and carried out by a well-known group of researchers and including a new investigator. The group has previously published several papers presenting analyses related to this research, however the comparison of complications associated with different methods of POP surgery is new to my knowledge.

This paper is clearly written.
The background explains the rationale for the research.
The methods are described in detail providing all definitions as required. Data handling and analysis are presented clearly.
The results are presented in detail, with each step of the analysis described, with supplementary analysis details provided in supplementary tables.
The discussion is long and detailed.

This is an unusually complete description of a straightforward study. The paper length could

be reduced a little by transferring Tables 1 and 2 to the appendices. These tables are already available in a paper by Mattisson et al 2019.

Author's response: We appreciate the Reviewer's input to review and give this positive comment. We also appreciate the suggestion of transferring Tables 1 and 2 to the appendices. However, if the length of the revised manuscript fits within the requirements of the journal we would prefer to keep them in the manuscript considering that they provide the reader essential information for the evaluation of between-group differences. Additionally, reviewers #1 and #2 found perioperative characteristics quite important when assessing the occurrence of complications in each surgical group.

Statistical Editor (Comments to the author):

lines 46-48: Need to cite pairwise stats test to support that one group had significantly higher rate. The comparison of all 3 groups merely tests whether the variation is due to random chance, not that one particular group was "highest", that may be true nominally, but needs statistical proof. In Abstract, should cite the count within each surgical cohort, not just the overall total.

Author's response: We thank the reviewer for this valuable comment. Lines 43-44 in the Abstract has been revised and the count within each surgical cohort added. The original version of the abstract stated: "Within one year after surgery 11.2% of women had at least one complication, majority of which occurred within two months." The revised abstract states: "Within one year after surgery 11.2% of women had at least one complication: 10.9% after native tissue repair, 11.7% after transvaginal- and 13.5% after abdominal mesh repair."

Differences between two surgical groups were tested with Bonferroni-corrected Chi-Square test (Fisher's Exact). The lines 46-48 have been revised and pairwise statistical significance added, as requested. We also apologize for an error in the reporting of statistical significance between TVM and AM groups in this line. The accuracy of each pairwise testing has since been double checked and no further errors were detected. Lines 46-48 previously stated: "Complication related reoperations occurred significantly more often after AM repair (5.2% vs NTR 1.2% and TVM 3.0%, p=.002)." The revised abstract states: "Complication related reoperations occurred significantly more often after abdominal mesh repair than native tissue surgery (5.2% vs 1.8%, *p*=.001)."

lines 225-240 and Table 5: The stats tests used (chi-square or Fisher's) do not allow identification of one of the three cohorts as being significantly different, but rather tests whether the distribution of adverse outcomes among the 3 cohorts is random. Need to support statements with pair-wise tests or modify the statements.

Author's response: We thank the reviewer for this valuable comment. As stated in the reply to the previous comment, the results were obtained by pairwise testing (Bonferroni-corrected Chi-Square test). The manuscript has been revised with the addition of note to pairwise differences in tables 3-5. Significance between two surgical

groups is indicated by a footnote indicating the use of Bonferroni-corrected pairwise testing, for example: “Significant difference between xxx and xxx (Bonferroni-corrected pairwise testing, p= xxx).”

The use of Bonferroni-corrected pairwise testing has been added to the Methods section of the manuscript as follows: “Bonferroni-corrected tests were used to assess pairwise differences between groups.”

Also, *p*-values have now been added to those parts of the manuscript mentioning statistically significant in between group differences:

Lines 193-195 prior: “Perioperative bladder injuries occurred significantly more often in both mesh groups compared to NTR (0.2% vs 1.4% in TVM and 1.6% in AM group, p<.001), with no difference between the mesh groups.” Revised line states: “Perioperative bladder injuries occurred significantly more often in both mesh groups compared to NTR (0.2% vs 1.4% in TVM, *p*=.002, and 1.6% in AM group, *p*=.006), with no difference between the mesh groups.”

Lines 196-198 prior: “The overall rate of complication related reoperations during one year after surgery was highest in AM group (5.6%), which was higher in comparison to other surgical groups (NTR 0.1% and TVM 2.6%, p=.002).” Revised line (with corrected %-values and added pairwise p-values): “The overall rate of complication related reoperations during one year after surgery was highest in AM group (5.2%) in comparison to other surgical groups (NTR 1.8%, p=.001, and TVM 3.0%, p=.213).”

Lines 231-233 prior: “Sixteen women (6.4%) in AM group required surgical treatment of complication under general anesthesia (grade 3b), which was significantly higher than in NTR (1.3%) or TVM (1.2%) groups.” Revised line states: “Sixteen women (6.4%) in AM group required surgical treatment of complication under general anesthesia (grade 3b), which was significantly higher than in NTR (1.3%, *p*<.001) or TVM (1.2%, *p*<.001) groups.”

Table 6: Should round all ORs, aORs and their CIs to nearest 0.01, not to 0.001 precision. Since CIs are given, no need to include p-values. Could embolden the associations that were statistically significant. The groups TV or abd Mesh have relatively fewer patients, with lower absolute counts of adverse outcomes and thus may represent over fitted models.

Author’s response: We thank the statistical reviewer for this valuable comment. Table 6 as well as Appendix 1 have been revised by rounding the ORs, aORs and their CIs to the nearest 0.01. We agree with the reviewer that the smaller number of patients in the TVM and AM groups may result to overfitted models. For this reason, we have emphasized the actual numbers (proportions) instead of *P*-values or statistical significance. Statistically significant associations have been bolded and *P*-values have been removed.

EDITOR COMMENTS:

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

> **Author's response:** OPT-IN: Yes, please publish my point-by-point response letter.

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

> **Author's response:** The disclosures of each coauthor have been confirmed as requested.

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.

> **Author's response:** The transparency declaration statement has been included in the cover letter as requested.

4. Please submit a completed STROBE checklist and a completed RECORD checklist.

Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of

Internet e-surveys
(CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

Author's response: A completed STROBE checklist and a completed RECORD checklist have been submitted as requested.

5. Your study uses ICD-10 data, please make sure you do the following:

a. State which ICD-10-CM/PCS codes or algorithms were used as Supplemental Digital Content.

Author's response: A list of ICD-10- codes along with Nordic Classification of Surgical Procedure (NCSP) codes used in this study have been provided as a separate file along with the revised manuscript.

b. Use both the diagnosis and procedure codes.

Author's response: As stated in the response to Q5b both ICD-10 and NCSP codes have been used.

c. Verify the selected codes apply for all years of the study.

Author's response: We have verified that selected codes apply for all years of the study.

d. Conduct sensitivity analyses using definitions based on alternative codes.

Author's response: To our best knowledge there is no need to conduct sensitivity analyses considering the coding used (ICD-10 and NCSP).

e. For studies incorporating both ICD-9 and ICD-10-CM/PCS codes, the Discussion section should acknowledge there may be disruptions in observed rates related to the coding transition and that coding errors could contribute to limitations of the study. The limitations section should include the implications of using data not created or collected to answer a specific research question, including possible unmeasured confounding, misclassification bias, missing data, and changing participant eligibility over time.

Author's response: Only ICD-10 codes were used in this study.

f. The journal does not require that the title include the name of the database, geographic region or dates, or use of database linkage, but this data should be included in the abstract.

Author's response: The requested data are provided in the abstract of originally submitted manuscript.

g. Include RECORD items 6.3 and 7.1, which relate to transparency about which codes, validation method, and linkage were used to identify participants and variables collected.

Author's response: The requested RECORD items are provided in the manuscript and supplementary files.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Author's response: We have revised the manuscript and assure the use of appropriate reVITAlize definitions in our manuscript.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

Author's response: We have revised the manuscript and made sure that the revised version does not exceed 22 pages, as requested. The word count for the manuscript and abstract are presented at the cover page of the revised manuscript.

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

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

Author's response: As stated at the initial submission of this manuscript, no financial support was provided for this study. The material costs for FINPOP study were provided by the Finnish Society of Gynecological Surgery, a non-profit organization.

All persons that contributed to this work have been reported in the manuscript (leading author and co-authors).

Preliminary results of this study have been presented orally at the Nordic Congress of Gynecological Endoscopy (NCGE) in Helsinki on June 8th, 2019.

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

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

> **Author's response:** The abstract has been revised and checked carefully as requested and the length follows the journal guidelines. Word count is provided on the cover page of the revised manuscript.

10. 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.

> **Author's response:** The use of abbreviations and acronyms have been revised to meet the journal guidelines.

11. Line 274 and elsewhere: 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.

> **Author's response:** The virgule symbol has been removed as requested. Line 274 previously stated: "Mesh complication was defined as mesh exposure or any mesh-related adverse event requiring surgical intervention and/or at least partial removal of mesh." The sentence has been revised as follows: "Mesh complication was defined as mesh exposure or any mesh-related adverse event requiring surgical intervention with or without partial or total removal of mesh."

12. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

Author's response: We have revised the Abstract and Results sections as requested by the Editor. We would prefer to report the proportion of women who had complications in each group as this is an important outcome of the study. Adding mean differences to the abstract would extend the word count beyond the limit of 300. We would like to point out that the adjusted odds ratios for complications are also reported in the revised abstract.

The data presentation of our manuscript has now been revised to meet the journal guidelines. For this study, the use of NNTb, NNTh or the outcome of the comparison in U.S. dollar amounts is not relevant.

12. 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.

Author's response: We have reviewed the journal's Table Checklist to make sure that our tables conform to journal style.

13. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

Author's response: The supplemental files have been revised as requested. The references have also been revised to meet the journal guidelines.

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

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

Author's response: If our manuscript will be accepted we would prefer traditional publishing route.