Date: Jan 08, 2021
To: "Avery Whitis" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-2634

RE: Manuscript Number ONG-20-2634

Retrospective Cohort Study Comparing Post-Operative Lower Extremity Neuropathy with Boot versus Candy Cane Stirrups

Dear Dr. Whitis:

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 29, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

The authors present a retrospective study on neuropathic injury in candy cane versus boot stirrups. This is an important topic for decreasing post operative and iatrogenic injury. Overall I thought this was a reasonably well written manuscript that was not over reaching with important hypothesis generating potential. There are some issues that should be addressed.
Specific comments:
1) Line 27-29; Dorsal lithotomy is not associated with all of the injuries listed in this line. Please adjust st to truly reflect the neuropathies that this position entails.
2) Lines 41-44; A figure or picture showing proper lithotomy position would be helpful
3) Line 75-76; Was the operating surgeon contacted to confirm the neuropathy present?
4) Line 78-80; I am unsure why you have chosen VTE as a secondary outcome? This does not seem related to neuropathy and is a totally different process. Am I missing something here? It is almost as if you are trying to answer two separate questions in this study.

5) Line 85: I am concerned about this- was this a pre-planned interim analysis? If you performed a power calculation it seems that you should have abstracted and analyzed that many charts. If you found a sig difference with 1000 less charts is your power analysis and initial assumption false? This does not make sense to me.

6) Line 91; did you chose a $p < .1$ as significant? if so you will need to justify as to why.

7) It is interesting that your groups seem to be fundamentally different. Why are some many demographic and surgical parameters (operative time, anesthesia, BMI) different between the groups? This introduces substantial bias.

Reviewer #2:

A few queries and suggestions on the paper, listed by line number in the manuscript:
1. Methods--line 53. Were records de-identified prior to review? If the records were not de-identified, did you obtain consent?
2. Line 56. Might be more appropriate to state that patient records were screened for inclusion rather than "patients" being "included".

3. Line 68. How did you define "surgery type"? All that is listed in the tables are routes of surgery, which I would consider to be different than surgery type.
4. Line 85. In your power calculation, did you assume unequal group numbers or plan a ratio of boot to candy-cane cases?
5. Line 86. Was this a planned interim analysis? If not, why was it conducted?
6. Line 94. Consider wording this as "patient records" versus "patients". From what you state in the methods section, you evaluated records and not actual patients for inclusion.
7. Line 101. Did you compare the procedure types between the groups? You state differences in numbers, but no mention of whether this is different between the stirrup groups. Should this have been included in the regression as a co-variate? Laparoscopic adnexal surgery and sacral colpopexy are very different procedures than a vaginal hysterectomy.
8. Table 2. There are some 6 and even 8 hour long cases on this list. I find that to be very unusual for benign gynaecology cases. What were these cases? That might be useful information to be included in Table 2, other than just "laparotomy" or "vaginal".
9. Lines 161-165. For points in the discussion section, recommendations should be based on your data set or backed up from other sources. What is the evidence that these recommendations are effective? They sound like common sense, but does it work? (or potentially cause harm?)
10. Line 173. Is the absence of neuropathy specifically noted in the records? This is an important point of distinction as you are using comparative statistics making an assumption that lack of documentation equates absence of the condition. It would be useful for the readers to know how many were assessed and had no documented neuropathy versus those that essentially had "missing data" that you are assuming to be "no neuropathy".
11. Line 178. How do you know that "any neuropathy not documented is probably less likely to be of clinical relevance"?
12. References. The formatting of a number of the references is not correct. There appears to be a cut & paste formatting error that occurred here.

Reviewer #3:

This was a retrospective cohort study comparing the incidence of lower extremity neuropathy in women undergoing benign gynecologic surgery using candy cane versus boot stirrups.

Abstract:
1) Please edit the Objective and Conclusion to include "women."

Methods:
1) Please specify who performed the manual review of the electronic medical record. Was it one individual, many individuals and was there any standardized data collection sheet created for the manual extraction of data and was the data entered directly into the web-based data platform? Did the individual or individuals performing the review undergo any formal standardized training for extraction of data? Please describe the web-based data platform.
2) It is not clear where in the electronic medical record the information was found regarding the diagnosis of peripheral neuropathy. Was the information identified after reading surgeons' postoperative examinations/notes? Where in the electronic medical record was the information that met the definition of "neuropathy" (lines 76-78) found? Please specify in more detail.

Results:
1) Figure 1 is missing but then appears at the very end. Please correct.
2) Table 2 Neuropathy cases. The "Pain or paresthesia" column does not line up horizontally with the other columns. Please correct.
3) Please note that 9 patients in the Boot group had persistent symptoms compared to 6 patients in the candy cane group (Table 2). Please explain these results in the Discussion section. Although lower extremity peripheral neuropathy occurred less often in the boot cohort, there were more patients in that group who had persistent symptoms.

STATISTICS EDITOR COMMENTS:

Lines 18-21: Should designate adjusted ORs as aORs, not as ORs.

Table 1: Would be informative to demonstrate the rates of neuropathy for boot vs candy cane, when stratified by surgical duration (perhaps by quartiles of the aggregate time?)

lines 90-92, 115-118 and Table 3: The number of adverse events totaled 50, with 6 variables entered as adjustors. This makes the model potentially over fitted. The Authors use a matching algorithm (eg, propensity matching) to match patients by age, BMI etc and then corroborate the associations. In the footnote, care should be used in employing the phrase "predictors of neuropathy".

Table 3: In the footnote, care should be used in employing the phrase "predictors of neuropathy". In a mathematical sense, the variables as as predictors, but the study design limits conclusions based on associations, not causation. The number of instances of VTE is very low and there is insufficient power to generalize the NS association

EDITORIAL OFFICE COMMENTS:

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

2. 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. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

4. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works.

Please cite FPM&RS Short Oral 95 where applicable.

5. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), 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.

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. 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. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

13. 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%").

14. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top).

15.
Figure 1: okay

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

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

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

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

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

16. 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.

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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. Do not omit your responses to the Editorial Office or Editors' comments.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 29, 2021, 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

[redacted]

1/18/2021

Dear Editor,

We wish to re-submit an original research article entitled "Retrospective Cohort Study Comparing Post-Operative Lower Extremity Neuropathy with Boot versus Candy Cane Stirrups" for consideration by Obstetrics and Gynecology. Please find attached our updated manuscript as well as the point-by-point response to the comments from the reviewers and editor.

We also must share an additional, important piece of information. During the process of making our revisions we realized that the surgical time for one of the neuropathy cases was incorrect in our database. One patient in the candy cane cohort who had a neuropathy had an incorrect value of 467 minutes in the database. We updated this to the correct value of 133 minutes. This corresponds to line 44 of Table 2. Additionally, we re-ran all of the relevant outcomes that this change could have impacted. The only changes were to the descriptive statistics for the surgical time of the candy cane cohort. There was no change to the primary outcome or the results of the logistic regression. Furthermore, we re-verified all of the other surgical times for neuropathy cases to ensure there were no additional errors.

[redacted]

REVIEWER COMMENTS:

Reviewer #1:

The authors present a retrospective study on neuropathic injury in candy cane versus boot stirrups. This is an important topic for decreasing post operative and iatrogenic injury. Overall I thought this was a reasonably well written manuscript that was not over reaching with important hypothesis generating potential. There are some issues that should be addressed.
Specific comments:
1) Line 29; Dorsal lithotomy is not associated with all of the injuries listed in this line. Please adjust st to truly reflect the neuropathies that this position entails.

Changed as requested.

2) Lines 41-44; A figure or picture showing proper lithotomy position would be helpful.

Figures have been added. We obtained permission from Elsevier and will upload the license with revised manuscript submission.

3) Line 70-71: Was the operating surgeon contacted to confirm the neuropathy present?

The operating surgeon was not contacted or alerted to the neuropathy by the research team. Due to the retrospective nature of the study, having the research team discuss with the operating surgeon a case that occurred 5-10 years ago was not feasible as several of the operating surgeons are no longer at our institution.

4) Line 80; I am unsure why you have chosen VTE as a secondary outcome? This does not seem related to neuropathy and is a totally different process. Am I missing something here? It is almost as if you are trying to answer two separate questions in this study.

We agree that the logic for including this as a secondary outcome is not immediately obvious. We considered this to simply be an “exploratory” outcome, hypothesizing that method of immobilization of the lower extremity could alter the risk of VTE. We tried to include language in lines 132-135 that explains the logic for this. That being said, if the editor prefers we simply remove this outcome from the manuscript because it could be confusing to readers, we are happy to do so.

5) Line 109: I am concerned about this- was this a pre-planned interim analysis? If you performed a power calculation it seems that you should have abstracted and analyzed that many charts. If you found a sig difference with 1000 less charts is your power analysis and initial assumption false? This does not make sense to me.

This was not a pre-planned interim analysis. This analysis was performed in order to meet a deadline for submission to a meeting. However, upon performing the analysis, we were pleased to see that we had significant findings. We reviewed this decision with the biostatistician consultant at our institution who felt that this was an acceptable and appropriate approach. This may be due to the larger difference in the primary outcome between groups than we initially anticipated.

6) Line 115; did you chose a $p < .1$ as significant? if so you will need to justify as to why.

We did not choose $p<0.1$ as the threshold for significance for the primary outcome. We only used $p<0.1$ as the threshold for adding variables into the logistic regression.

7) It is interesting that your groups seem to be fundamentally different. Why are some many demographic and surgical parameters (operative time, anesthesia, BMI) different between the groups? This introduces substantial bias.

We added an acknowledgement of this in the discussion section paragraph on limitations.

Reviewer #2:

A few queries and suggestions on the paper, listed by line number in the manuscript:
1. Methods--line 68. Were records de-identified prior to review? If the records were not de-identified, did you obtain consent?

A waiver of consent was given for this study. We added this information.

2. Line 67. Might be more appropriate to state that patient records were screened for inclusion rather than "patients" being "included".

This change was made.

3. Line 86. How did you define "surgery type"? All that is listed in the tables are routes of surgery, which I would consider to be different than surgery type.

We agree with the comment and changed this wording to match the table.

4. Line 106. In your power calculation, did you assume unequal group numbers or plan a ratio of boot to candy-cane cases?

We had not pre-planned for unequal group numbers in our original power calculations.

5. Line 109. Was this a planned interim analysis? If not, why was it conducted?

This same concern from reviewer #1 is addressed above.

6. Line 118. Consider wording this as "patient records" versus "patients". From what you state in the methods section, you evaluated records and not actual patients for inclusion.

We agree, and this was changed.

7. Line 126. Did you compare the procedure types between the groups? You state differences in numbers, but no mention of whether this is different between the stirrup groups. Should this have been included in the regression as a co-variate? Laparoscopic adnexal surgery and sacral colpopexy are very different procedures than a vaginal hysterectomy.

We agree that this is an interesting question, and we did consider this issue. However, we made the decision not to include the specific type of surgery as a co-variate for two reasons. First, there is no straight-forward way to separate specific procedures into mutually exclusive groups. For example, consider patients having a laparoscopic sacral colpopexy. Some will only have a sacral colpopexy, some will have this combined with hysterectomy, others will also have a sling, and so on. Additionally, we felt that the specific procedure type was unlikely have a plausible pathophysiologic reason for contribution to lower extremity neuropathies.

8. Table 2. There are some 6 and even 8 hour long cases on this list. I find that to be very unusual

for benign gynaecology cases. What were these cases? That might be useful information to be included in Table 2, other than just "laparotomy" or "vaginal".

We have added a column in Table 2 with this information.

9. Lines 222-226. For points in the discussion section, recommendations should be based on your data set or backed up from other sources. What is the evidence that these recommendations are effective? They sound like common sense, but does it work? (or potentially cause harm?)

Appropriate citations have been added.

10. Line 240. Is the absence of neuropathy specifically noted in the records? This is an important point of distinction as you are using comparative statistics making an assumption that lack of documentation equates absence of the condition. It would be useful for the readers to know how many were assessed and had no documented neuropathy versus those that essentially had "missing data" that you are assuming to be "no neuropathy".

Thank you for this point. We clarified this important point starting at line 240.

11. Line 244. How do you know that "any neuropathy not documented is probably less likely to be of clinical relevance"?

We also made a clarification on this at line 244.

12. References. The formatting of a number of the references is not correct. There appears to be a cut & paste formatting error that occurred here.

We have fixed this error.

Reviewer #3:

This was a retrospective cohort study comparing the incidence of lower extremity neuropathy in women undergoing benign gynecologic surgery using candy cane versus boot stirrups.

Abstract:
1) Please edit the Objective and Conclusion to include "women."

This change was made.

Methods:
1) Please specify who performed the manual review of the electronic medical record. Was it one individual, many individuals and was there any standardized data collection sheet created for the manual extraction of data and was the data entered directly into the web-based data platform? Did the individual or individuals performing the review undergo any formal standardized training for extraction of data? Please describe the web-based data platform.

These additions were made in lines 72-74 and 91-95.

2) It is not clear where in the electronic medical record the information was found regarding the diagnosis of peripheral neuropathy. Was the information identified after reading surgeons' postoperative examinations/notes? Where in the electronic medical record was the information that met the definition of "neuropathy" (lines 76-78) found? Please specify in more detail.

These additions were made in lines 92-101.

Results:
1) Figure 1 is missing but then appears at the very end. Please correct.

The figure is located within the results section per the author instructions.

2) Table 2 Neuropathy cases. The "Pain or paresthesia" column does not line up horizontally with the other columns. Please correct.

This correction was made.

3) Please note that 9 patients in the Boot group had persistent symptoms compared to 6 patients in the candy cane group (Table 2). Please explain these results in the Discussion section. Although lower extremity peripheral neuropathy occurred less often in the boot cohort, there were more patients in that group who had persistent symptoms.

Thank you for this comment. This is true that are more individual patients with persistent symptoms in the boot cohort compared to the candy cane cohort. However, this is most likely a function of the boot group being a larger cohort overall. The frequency of these events is actually very similar between the two cohorts. There were 9/29 (31.0%) with persistent symptoms in the boot cohort compared to 6/21 (28.6%) in the candy cane cohort. This was addressed line 137-138.

STATISTICS EDITOR COMMENTS:

Line 21: Should designate adjusted ORs as aORs, not as ORs.

This change was made.

Table 1: Would be informative to demonstrate the rates of neuropathy for boot vs candy cane, when stratified by surgical duration (perhaps by quartiles of the aggregate time?)

Thank you for this great recommendation. We added Table 4 to present this information.

lines 118-120, 131-135 and Table 3: The number of adverse events totaled 50, with 6 variables entered as adjustors. This makes the model potentially over fitted The Authors use a matching algorithm (eg, propensity matching) to match patients by age, BMI etc and then corroborate the associations. In the footnote, care should be used in employing the phrase "predictors of

neuropathy".
Table 3: In the footnote, care should be used in employing the phrase "predictors of neuropathy". In a mathematical sense, the variables as as predictors, but the study design limits conclusions based on associations, not causation. The number of instances of VTE is very low and there is insufficient power to generalize the NS association

We changed the wording in all of these instances to state that the variables were, “associated with” rather than, “predictors of…”. We also added language in lines 148 to clarify the editor’s point about the low incidence of VTE.

EDITORIAL OFFICE COMMENTS:

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

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.

We have added a disclosure for author Edison Chen, BS.

3. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.
see line 71-74

4. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works.
Please cite FPM&RS Short Oral 95 where applicable.
This short oral presentation was a preliminary presentation of this original research, as disclosed in the prior cover letter.

5. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), 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.

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6, 7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7, 8
Bias	9	Describe any efforts to address potential sources of bias	16,17
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed	8

		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	8, 10
Outcome data	15*	Report numbers of outcome events or summary measures over time	11-13

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	13-14
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	13-14
Discussion			
Key results	18	Summarise key results with reference to study objectives	14-15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

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.
This was reviewed and did not lead to any changes in the 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.
Without the cover letter, page limits and word limits are not exceeded.

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).
Prior presentation was noted in the original cover letter.

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.
This was reviewed.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.
Abstract word count is 290.

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.
This was reviewed.

11. 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.
This symbol was only used when expressing data or measurements.

12. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring

(for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.
Two instances of the word “provider” was replaced by “physician”

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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%"). This was reviewed.

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University of Iowa