

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.*

Personal or nonessential information may be redacted at the editor's discretion.

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

obgyn@greenjournal.org.

Date: Nov 01, 2019
To: "Annie M. Dude" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1895

RE: Manuscript Number ONG-19-1895

Maternal sense of control during childbirth and infant feeding method

Dear Dr. Dude:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Nov 22, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

This is a secondary analysis of the ARRIVE (A Randomized Trial of Induction Versus Expectant Management) trial. This is a multi-center trial of women who underwent either expectant management or induction at 39 weeks of gestation. Women had to have completed a measure of women's feelings of control over the childbirth process, had a live birth, and had a postpartum visit between 4 and 8 weeks' postpartum.

After adjustment for confounders, perceived control during childbirth was not associated with breastfeeding at 4-8 weeks postpartum. Rather, whether a woman was breastfeeding was associated with demographic characteristics such as race, age, ethnicity, insurance status, and marital status, as well as variables pertaining to the pregnancy including mode of delivery and whether the neonate went to the intermediate or intensive care unit.

Disclosures: None to report.

Human subjects: The trial was approved by the Institutional Review Boards of all participating centers.

Abstract:

1. The abstract is well written and is representative of the article.

Introduction:

2. The purpose is clear and concise, the background is succinctly described.

Methods:

3. Methods are well described and the procedures used are presented in great detail.

Results:

4. The data answered the study question.

Discussion:

5. The discussion is well written and the data support the conclusions. The limitations are well described.

References:

6. The references seem pertinent.

Tables:

7. Tables 1,2 and 3: It might be useful to include quintile values in a legend.

REVIEWER #2:

Dude et al present a secondary analysis of the ARRIVE trial and evaluate the relationship between maternal sense of control and breastfeeding practices. The manuscript is well written and uses a validated survey to assess maternal control. The authors find no relationship between control and LAS scores after adjusting for confounders. The clinical significance of the research is somewhat limited.

Introduction: clearly states the hypothesis. In paragraph starting with line 107 the authors describe potential associations with high LAS scores and lower breastfeeding rates. This may be an area to comment on the additional associations of low breastfeeding rates

Methods:

123- did the women in the trial complete any additional questionnaires (i.e. postpartum depression scales). Was information collected on onset of lactogenesis II?

Results:

The authors chose to use a large number of confounding variables. Was the lack of significance in the adjusted model driven by a particular confounder?

Discussion: The authors do a nice job of commenting on a major weakness of the study in that the LAS is likely influenced by factors also associated with breastfeeding. The multiple confounders in this study, I believe, limit its clinical significance. The paper would be strengthened by a short discussion of clinical significance of this study.

REVIEWER #3:

1. I think the Supplemental Table showing the details of the 848 excluded patients alongside the values for the 5185 included patients has added considerably to the understanding of this study and deserves applause.

2. The authors have highlighted the strengths of their study being the large numbers involved of racially diverse women all delivering for the first time in a number of different institutions. They have also acknowledged those women who participated in the study could represent a selection bias and that the method of feeding by the participants was 'self-reported'.

3. While acknowledging the limitations of this study and accepting there may be no association between feelings of 'control during labour' determined by the LAS score, the authors also accept specific factors that potentially influence the LAS score could individually impact upon the success of breastfeeding.

4. Since only nulliparous women were studied, this should be stated in the Conclusion section of the 'Abstract'.

5. My only criticism of the study is the assessment of successful breastfeeding was only made once at 4-8 weeks following delivery, while further worthwhile information might have been obtained with a subsequent follow-up assessment at perhaps 12-16 or more weeks following delivery.

STATISTICAL EDITOR'S COMMENTS:

1. lines 81-83: Need to provide a flow diagram indicating how many women were eligible vs those that met all the inclusion criteria and were then analyzed. Also, Suppl Table 1 is important and should be included in main text. Although not a large proportion of the final cohort, the baseline differences in key areas are important enough that the estimates in Table 3 may have been biased by the missing data.

2. lines 174-178: Although these differences were statistically significant for comparing these large samples, the IQRs were wide and the differences in median LAS scores were modest. Were those differences clinically important or put another way, could the LAS score be used prospectively to allocate which women were more likely to be breastfeeding?

3. General: It seems unclear whether the primary outcome was breastfeeding exclusively or combination of breast and formula feeding vs formula feeding. Table 2 appears to have 8 comparisons, each with an inference threshold of $p < .05$ or

95% CIs. There is no adjustment for multiple hypothesis testing. Using a stricter inference threshold, all comparisons except LAS quintile 2 (breastfeeding vs formula) would become NS.

4. Table 2: Although the results would be unadjusted, it might be useful to show the reader a histogram of the proportion of women breastfeeding in the 5 quintiles. Would also be of interest to include the range of LAS scores in each quintile.

EDITORIAL OFFICE COMMENTS:

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

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

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

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

5. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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

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

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

8. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with

the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

9. 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.

10. 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.

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

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

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

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

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Nov 22, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2018 IMPACT FACTOR: 4.965

2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>). Please contact the publication office if you have any questions.

November 25, 2019

Dear Dr. Chescheir,

Thank you for the opportunity to revise our paper, 'Maternal sense of control during childbirth and infant feeding method' for consideration for publication in Obstetrics & Gynecology.

Specific comments to reviewer questions are as follows:

REVIEWER #1:

Abstract:

1. The abstract is well written and is representative of the article.

Introduction:

2. The purpose is clear and concise, the background is succinctly described.

Methods:

3. Methods are well described and the procedures used are presented in great detail.

Results:

4. The data answered the study question.

Discussion:

5. The discussion is well written and the data support the conclusions. The limitations are well described.

References:

6. The references seem pertinent.

Response: Thank you.

Tables:

7. Tables 1,2 and 3: It might be useful to include quintile values in a legend.

Response: These have been added to Table 2.

REVIEWER #2:

Dude et al present a secondary analysis of the ARRIVE trial and evaluate the relationship between maternal sense of control and breastfeeding practices. The manuscript is well written and uses a validated survey to assess maternal control. The authors find no relationship between control and LAS scores after adjusting for confounders. The clinical significance of the research is somewhat limited.

Introduction: clearly states the hypothesis. In paragraph starting with line 107 the authors describe potential associations with high LAS scores and lower breastfeeding rates. This may be an area to comment on the additional associations of low breastfeeding rates.

Response: We did address more extrinsic barriers to breastfeeding in the paragraph above, as well as intrinsic barriers in this paragraph. We would be happy to include others as suggested.

Methods:

123- did the women in the trial complete any additional questionnaires (i.e. postpartum depression scales).

Response: Women were asked to rate their pain in labor on a 10 point Likert scale. Postpartum depression scales were not collected as part of the ARRIVE trial.

Was information collected on onset of lactogenesis II?

Response: This information was not collected.

Results:

The authors chose to use a large number of confounding variables. Was the lack of significance in the adjusted model driven by a particular confounder?

Response: All of the confounders ultimately included in the final model were significant at the $p < 0.05$ level. We adjusted the LAS score with one variable at a time. Once the LAS score is adjusted by just race/ethnicity or just private insurance, the association with type of feeding becomes non-significant. Using backward selection, the first variable to be eliminated from the full model is the LAS score.

Discussion: The authors do a nice job of commenting on a major weakness of the study in that the LAS is likely influenced by factors also associated with breastfeeding. The multiple confounders in this study, I believe, limit its clinical significance.

Response: Thank you for this comment. An alternative interpretation is that other factors (such as extrinsic barriers to breastfeeding, including lack of time off work) matter more for breastfeeding than control over the labor process.

The paper would be strengthened by a short discussion of clinical significance of this study.

Response: We have added a sentence to the discussion section regarding the clinical significance of the study.

REVIEWER #3:

1. I think the Supplemental Table showing the details of the 848 excluded patients alongside the values for the 5185 included patients has added considerably to the understanding of this study and deserves applause.

Response: Thank you. We have now included this as Table 1 and have renumbered the other tables accordingly.

2. The authors have highlighted the strengths of their study being the large numbers involved of racially diverse women all delivering for the first time in a number of different institutions. They have also acknowledged those women who participated in the study could represent a selection bias and that the method of feeding by the participants was 'self-reported'.

3. While acknowledging the limitations of this study and accepting there may be no association between feelings of 'control during labour' determined by the LAS score, the authors also accept specific factors that potentially influence the LAS score could individually impact upon the success of breastfeeding.

4. Since only nulliparous women were studied, this should be stated in the Conclusion section of the 'Abstract'.

Response: This has been added to the relevant section of the abstract.

5. My only criticism of the study is the assessment of successful breastfeeding was only made once at 4-8 weeks following delivery, while further worthwhile information might have been obtained with a subsequent follow-up assessment at perhaps 12-16 or more weeks following delivery.

Response: Thank you for this suggestion; this is quite true. These data were collected as part of the ARRIVE trial, the main focus of which was not breastfeeding or even the postpartum period per se. Thus, these data were only collected once. We have added a sentence to the limitations section regarding the relatively short follow up.

STATISTICAL EDITOR'S COMMENTS:

1. lines 81-83: Need to provide a flow diagram indicating how many women were eligible vs those that met all the inclusion criteria and were then analyzed.

Response: We have created this and added it as Figure 1.

Also, Suppl Table 1 is important and should be included in main text. Although not a large proportion of the final cohort, the baseline differences in key areas are important enough that the estimates in Table 3 may have been biased by the missing data.

Response: We have changed the supplemental table to Table 1, and have added a section in the limitations regarding how these women with missing data may have biased the sample.

2. lines 174-178: Although these differences were statistically significant for comparing these large samples, the IQRs were wide and the differences in median LAS scores were modest. Were those differences clinically important or put another way, could the LAS score be used prospectively to allocate which women were more likely to be breastfeeding?

Response: Our study did not show an association between the LAS score and breastfeeding. Therefore, in this study the LAS is not necessarily a useful tool to determine which women will be likely to breastfeed. We have added a sentence to the discussion addressing this. We have also added Figure 2, which visually shows this.

3. General: It seems unclear whether the primary outcome was breastfeeding exclusively or combination of breast and formula feeding vs formula feeding. Table 2 appears to have 8 comparisons, each with an inference threshold of $p < .05$ or 95% CIs. There is no adjustment for multiple hypothesis testing. Using a stricter inference threshold, all comparisons except LAS quintile 2 (breastfeeding vs formula) would become NS.

Response: We updated table 2 by transposing its rows and columns. We added a legend to indicate that the odds ratios presented in this table are from a multinomial logistic regression. The primary outcome was a multinomial outcome with three categories: 1. exclusive formula feeding (reference), 2. exclusive breastfeeding and 3. breastfeeding and formula feeding. These outcomes are mutually exclusive and exhaustive, and have a single reference category against which the other two categories are compared. The exposure variable is a single variable with 5 categories. Because only one model was run, no adjustment for multiple comparisons was made.

In addition, the frequencies and percentages that were presented in table 2 are now displayed in figure 2.

4. Table 2: Although the results would be unadjusted, it might be useful to show the reader a histogram of the proportion of women breastfeeding in the 5 quintiles. Would also be of interest to include the range of LAS scores in each quintile.

Response: We have included the range of LAS scores in each quintile in the Table 2 legend and added Figure 2 that shows the distribution of breastfeeding by LAS score quintile.

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.

Response: Opt – in – you may publish our point-to-point response letter.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

Response: I will confirm with my coauthors that all conflicts of interest are listed correctly.

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

Response: This was a secondary analysis of a clinical trial and therefore the policy is not applicable.

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

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

Response: We have followed the STROBE guidelines for this observational study.

5. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Response: We have used standardized definitions.

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

Response: We have not exceeded the word or page limits.

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

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

Response: We have checked the abstract, and provided a word count (302 words).

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

Response: This is not a randomized controlled trial (although it is a secondary analysis of an RCT).

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

Response: We only use standard abbreviations and acronyms. We define all acronyms.

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

Response: We do not use the virgule symbol.

11. 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 (NNT_h). 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%).

Response: We have standardized our data presentation. NNT is not relevant here.

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.

Response: Our tables conform to the journal style.

13. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely

available online immediately upon publication. An information sheet is available at <http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <http://edmgr.ovid.com/acd/accounts/ifaauth.htm>.

Response: We will not be publishing open access.