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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)*

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Transcutaneous Electrical Nerve Stimulation for Post-Cesarean Pain Control: A Randomized Controlled Trial

Dear Dr. Kurata:

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).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

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 Feb 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Abstract:
It is a bit misleading to call this a randomized, double-blinded, placebo-controlled trial as there were three arms and the no TENS arm was of course not blinded.

Introduction:
The authors mention that there is some data for TENS after gyn procedures. Which ones and what does the literature show? TENS has been trialed after CD as you mention in the discussion, with several studies. I would briefly mention here. TENS has been reported during labor, it might be interesting to discuss in the introduction or discussion.

Methods:
Why did the authors perform a three arm trial ant not just placebo TENS compared to active TENS? Is another paper planned?
Who placed the TENS units and how are they used?
Can the patient control it, can they turn it on and off and change the settings?
Please add a more detailed description of the survey.
Line 75- is this a standard TENS setting? How was this chosen?
How were patients monitored to ensure compliance with TENS?
Is the TENS placed above and below the bandage? Was the TENS removed for bandage removal?
Line 92- Patients received acetaminophen 1000mg IV q6hrs post-operatively, is this correct?
Line 108- This study is not really completely double (or triple?) blinded. I would change the abstract to reflect that as stated earlier.
Was a telephone survey also planned for any time after discharge?

Results:
Did the authors plan on a subgroup analysis of TENS vs no TENS, or active-TENS vs placebo- TENS?
Do the authors have any data on prescriptions for opioids after delivery?

Discussion:
Do the authors think there was a beta error and that is why there was no difference seen? Why do the authors think so few patients used opioids after cesarean? I think this is a significant and important finding. How does this compare to other literature? Was this related to the patient population, COVID, the hospital culture etc? I would add some additional background about how TENS works, given that the audience is OBGYN’s and not pain medicine.

Tables/Figures:
I would add a copy of the survey, perhaps as an Appendix.

Add a figure of the actual TENS unit alongside Figure 1.

Table 1: Why do the authors think that they have such a high preterm birth rate, especially as the majority of cases were scheduled repeat CD’s?

Reviewer #2:

In this study, the authors describe results of an RCT of the TENS unit for postoperative cesarean pain. They conduct a three-arm study to evaluate pain control and other parameters postoperatively. The manuscript is well-written and easy to follow. The sections provide significant detail and this addresses in a small scope an important question. My main concern is the way the 3-groups are compared and the ability to really say there is no difference when two groups are not compared (see below). I would suggest a different statistical analysis taking two-group differences into consideration or at least a greater rationale why all three groups were compared against each other (specifically the unblinded no TENS groups). Specific comments follow below:

Abstract:
- Line 18: Were characteristics similar across all three groups? Like a global test of difference?
- See methods: why were the three groups compared in total as opposed to specific tests: TENS vs. no TENS, TENS vs. placebo TENS which makes more sense especially given the results being very different in the no TENS group because I assume there will be a difference there.
- The authors report double blind: however, in the no TENS group, how is this blind if there was not a TENS unit.

Methods:
- the authors reports that this is a double blind study, however, one arm has no TENS unit placed so the patient cannot be blinded to this intervention. Please amend.
- primary outcome: why did the authors specifically chose 60 hours? as opposed to hospital duration or first 24 hours?
- can the authors clarify that all responses to pain questions, adverse reactions were all collected by telephone visit? Thus, only the primary outcome was ascertained by chart review and the other by telephone?
- in the methods, the authors do not describe the rationale behind the no TENS group as opposed to the TENS-placebo group.
- To this end, the analysis plan for 3 groups is not well-described. Would recommend two group comparisons as opposed to three group comparisons which may miss two-group differences.

Results:
-Table 1: The p-values for an RCT for 3 groups are included in the table and should not be presented
- Line 154-155: the global p-value if that is what is being used, only test for 3-group differences but not the direction of the difference.
- The main limitation of this study is the use of the 3-group comparison across the arms without any rationale for the inclusion of the no TENS group. I think the comparisons that make sense are TENS vs TENS placebo; TENS placebo vs. no TENS or even TENS vs no TENS. It is very hard to interpret the three group results. Less so for the secondary outcomes, but these comparisons should exist for the primary outcomes. Even excluding the no TENS group would make more sense in the interpretation of these findings.

Discussion: Provides clear rationale and discussion of the results without overstating findings
- However, while the authors found no difference, we cannot exclude that a difference exists. It could be that the size of the difference was too small to detect, i.e. underpowered or insufficient sample size to detect smaller differences
Reviewer #3:

Review for Obstetrics and Gynecology
Transcutaneous Electrical Nerve Stimulation for Post-Cesarean Pain Control: A Randomized Controlled Trial

First, I would like to thank the Editor(s) of Obstetrics and Gynecology Journal for the opportunity to review this article regarding transcutaneous electrical nerve stimulation for post-cesarean pain control.

Second, I would like to congratulate the authors of the article for their work.

Although caesarean section is the most common surgery in many countries, opioid dependence induced by postoperative analgesia is a less common problem, probably due to limited opioid use for the first 24 hours postoperatively. In view of this discrepancy, it may be useful for the authors to specify the protocol according to which the administration of opioids is extended up to 60 hours postoperatively. In my opinion, the reduced need for opioid administration time and the short duration of hospitalization are secondary results of the study but equal in importance to the main objective, and this aspect was very correctly highlighted.

Trying to reduce pain by electric stimulation is a current method tested in many areas. This original research is a well-designed clinical investigation. Sufficient information had been analyzed, rigorous evaluated, permitting pertinent conclusion. The tables and figures included are appropriate. The references are numerous and fair selected.

The importance of managing postoperative pain remains one of the challenges of all surgical branches, especially in obstetrics given the increasing prevalence of cesarean section. Given the results presented, as well as the idea of offering the possibility of decreasing the dose of opioids used in the management of postoperative pain, it would be interesting to note in the future whether opioid-exposed patients maintain the same results or to what extent they differ.

STATISTICS EDITOR COMMENTS:

Abstract and lines 129-134: Need to conform to our template for RCTs. The sample size calculation was based on a 25% decrease in mean MME from 6.5 tablets of oxycodone with an estimated SD = 3. Therefore the primary outcome should be formatted in a similar fashion. Comparison of median[IQR] of each cohort is not the same format or stats test. Could then provide the comparison of medians, since the data were non-normally distributed. The sample size/power calculation is based on comparing one group vs another, not for comparison among three groups or between 3 pairings. That would require a stricter alpha value and a larger sample size, due to multiple hypothesis testing.

Table 1: Since the groups were randomly allocated, should not present stats results for comparison of baseline variables. Any difference in baseline variables is due to random chance.

Table 2: Need to label this as one of the secondary outcomes.

Tables 2, 3, 4: Were pain scores and LOS normally distributed? If not, then should format as median(Range or IQR), rather than as mean ± SD and test non-parametrically.

Fig 3: Legend should include stats comparing the groups.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
   * Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
   * Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
   * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
   * Name the IRB or Ethics Committee institution in the Methods section (if applicable).
   * Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

4. 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.

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5. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

   Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

6. 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).

7. Figure 1: Is this original to the manuscript?
Figure 2: Are items in the exclusion box not mutually exclusive?
Figure 3: okay
All figures: Please upload as figure files on Editorial Manager.

Tables, figures, and supplemental digital content should be original. The use of borrowed material (e.g., lengthy direct quotations, tables, figures, or videos) is discouraged. If the material is essential, written permission of the copyright holder must be obtained.

Both print and electronic (online) rights must be obtained from the holder of the copyright (often the publisher, not the author), and credit to the original source must be included in your manuscript. Many publishers have online systems for submitting permissions requests; please consult the publisher directly for more information. Permission is also required for material that has been adapted or modified from another source.

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When you submit your revised manuscript, please upload 1) the permissions license and 2) a copy of the original source from which the material was reprinted, adapted, or modified (e.g., scan of book page(s), PDF of journal article, etc.).

8. 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.

9. 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 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

10. 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.
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* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology,
add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

11. 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; Reviews is 300 words; Case Reports is 125 words; Current Commentary articles is 250 words; Executive Summaries, Consensus Statements, and Guidelines are 250 words; Clinical Practice and Quality is 300 words; Procedures and Instruments is 200 words. Please provide a word count.

12. 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.

13. 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.

14. 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.

15. ACOG avoids using "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.

16. 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%)

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19. Figure 1: Is this original to the manuscript?
   Figure 2: Are items in the exclusion box not mutually exclusive?
   Figure 3: okay
   All figures: Please upload as figure files on Editorial Manager.

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.

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* 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 Feb 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD
Deputy Editor, Obstetrics

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd 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.
Dear Editor:

Thank you very much for the review of our manuscript Transcutaneous Electrical Nerve Stimulation for Post-Cesarean Pain Control: A Randomized Trial. We submit to you the revised manuscript and response to reviewers (next page). This manuscript is not under review by any other journals and will not be submitted elsewhere unless a final negative decision is made by the Editors of Obstetrics and Gynecology.

Nicole Kurata 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.

As stated in the prior cover letter, this study is registered on ClinicalTrials.gov (ID# NCT04399707, enrollment January 29, 2020 to March 8, 2021). This study was not officially registered on ClinicalTrials.gov until May 22, 2020, which was after subject enrollment had already begun. The trial was registered as a three-arm study, consistent with the outcomes submitted in the first draft. Based on reviewer comments, the authors have chosen to revise the study into a two-arm trial. Thus, the outcomes reported in our revised manuscript now differ than those previously registered.

The authors attest adherence to the GPP3 guidelines

The study was approved by the Western Institutional Review Board.

Written permission has been obtained from all persons named in the acknowledgments

The transcutaneous electrical nerve stimulation (TENS) units and electrodes used in this study were donated by Cardinal Health, however they were not involved with the study design, data analysis, or manuscript drafting.

Sincerely,

Nicole Kurata
Thank you very much for the review of this manuscript. Please find our responses below.

Abstract:
It is a bit misleading to call this a randomized, double-blinded, placebo-controlled trial as there were three arms and the no TENS arm was of course not blinded.

We agree with this comment and have revised the manuscript and abstract to reflect that the double-blinding involved the active vs placebo TENS arms.

Introduction:
The authors mention that there is some data for TENS after gyn procedures. Which ones and what does the literature show? TENS has been trialed after CD as you mention in the discussion, with several studies. I would briefly mention here.
TENS has been reported during labor, it might be interesting to discuss in the introduction or discussion.

Additional background and references on the use of TENS in obstetrics and gynecology have been added to the introduction.

Methods:
Why did the authors perform a three arm trial and not just placebo TENS compared to active TENS? Is another paper planned?

A three-arm study was initially chosen because the authors felt that having an arm with no TENS was a valuable comparison that represented a real-world control group (patients do not routinely use TENS after cesarean). If opioid use with TENS was decreased due to a placebo effect, this would still be clinically valuable information.

However, we agree with the reviewer comments and have decided to revise the study to two-arms comparing active TENS to placebo TENS. A secondary analysis evaluating for a placebo effect was done by comparing placebo TENS to no TENS.

Who placed the TENS units and how are they used?
Can the patient control it, can they turn it on and off and change the settings?

A member of the study team (either a resident or attending OB physician) placed the TENS units after the cesarean delivery. The TENS unit (both active and placebo) were turned on and remained on. Patients were able to adjust the intensity of the TENS unit as well as turn the device on and off according to their preference. The battery compartment, which also contained the settings for the device, was sealed close so that patients were not able to adjust the settings.

This information has been added to the methods.

Please add a more detailed description of the survey.
A copy of the survey was added as an appendix item

*Line 75-* is this a standard TENS setting? How was this chosen?

TENS settings used in this study aligned with those most commonly used at our institution following abdominal surgery. These settings are also similar to those used in prior work on TENS and postoperative pain (Parselius A, et al. Transcutaneous Electric Nerve Stimulation Reduces Acute Postoperative Pain and Analgesic Use After Open Inguinal Hernia Surgery: A Randomized, Double-Blind, Placebo-Controlled Trial. J Pain 2021;22:533-44. and Bjordal et al. Transcutaneous electrical nerve stimulation (TENS) can reduce postoperative analgesic consumption. A meta-analysis with assessment of optimal treatment parameters for postoperative pain. Eur J Pain 2003;7:181-8.)

*How were patients monitored to ensure compliance with TENS?*

Patients were encouraged to keep the TENS applied at the time of recruitment, but were free to remove it per their preference. We felt this approach represented a practical, real-world use of TENS.

*Is the TENS placed above and below the bandage? Was the TENS removed for bandage removal?*

The TENS was placed below the bandage. The TENS was not removed for bandage removal as it was placed below the bandage.

*Line 92-* Patients received acetaminophen 1000mg IV q6hrs post-operatively, is this correct?

Yes, they received acetaminophen 1,000 mg IV q6 hours post-op for the first 24 hours and then was switched to acetaminophen 650 mg PO q4 hours. There are also standard orders in our institution not to exceed 4000 mg of acetaminophen in 24 hours from all combined acetaminophen-containing products. Acetaminophen 1000 mg IV q6 is consistent with recommended dosing for postoperative pain (American Pain Society et al. Guidelines on the management of postoperative pain: A clinical practice guideline. J Pain 2016;17:131-57).

*Line 108-* This study is not really completely double (or triple?) blinded. I would change the abstract to reflect that as stated earlier.

The manuscript has been revised

*Was a telephone survey also planned for any time after discharge?*

We agree that postdischarge data would have been valuable, but a telephone survey was not planned after discharge. We felt this would be logistically challenging with high attrition and possibly biased participation. In addition, we did not have enough supplies to discharge the patients with their TENS units.

*Results:
Did the authors plan on a subgroup analysis of TENS vs no TENS, or active-TENS vs placebo- TENS?*
The statistical analysis has been revised for a primary outcome of active TENS vs placebo TENS for the primary outcome and placebo TENS vs no TENS as a secondary analysis.

**Do the authors have any data on prescriptions for opioids after delivery?**

We agree that this would have been interesting information but this was not collected.

**Discussion:**

**Do the authors think there was a beta error and that is why there was no difference seen?**

Given the low absolute amount of opioids used by all groups, we suspect that there was unlikely any clinically significant effect of TENS on opioid use in our study population. However, this does not preclude the possibility of a beta error and this has been added to the discussion.

**Why do the authors think so few patients used opioids after cesarean? I think this is a significant and important finding. How does this compare to other literature? Was this related to the patient population, COVID, the hospital culture etc?**

We agree that the low opioid use in this study is an important and interesting finding and adds to the very limited current literature on this topic. We do not have any evidence to suggest that this is related to our specific patient population or hospital culture. However, all patients did receive scheduled NSAIDs and acetaminophen, which is likely an important factor. In addition, we excluded certain groups at increased risk for higher opioid requirements, such as those with chronic opioid use. We would advocate for further study of TENS in those with risk factors for increased opioid needs.

*I would add some additional background about how TENS works, given that the audience is OBGYN's and not pain medicine.*

Information on the mechanism of TENS has been added to the introduction.

**Tables/Figures:**

*I would add a copy of the survey, perhaps as an Appendix.*

The survey was added as an Appendix item.

*Add a figure of the actual TENS unit alongside Figure 1.*

TENS units vary in looks by manufacturer and model. We hope to avoid any appearance of suggesting or promoting a specific commercial product. However, more detail has been added to Figure 1 in order to clarify the basic components of this device.

**Table 1: Why do the authors think that they have such a high preterm birth rate, especially as the majority of cases were scheduled repeat CD's?**

The hospital where this study was conducted is a tertiary referral center for the Pacific Rim, thus we might expect a disproportionately higher rate of preterm deliveries compared to other facilities. In
addition, cesarean is more common among preterm compared to term neonates (Delnord M et al. Varying gestational age patterns in cesarean delivery: an international comparison. BMC Pregnancy and Childbirth 2014). This would predispose to an overrepresentation of preterm deliveries in a study population limited to cesarean births.

Reviewer #2:

My main concern is the way the 3-groups are compared and the ability to really say there is no difference when two groups are not compared (see below). I would suggest a different statistical analysis taking two-group differences into consideration or at least a greater rationale why all three groups were compared against each other (specifically the unblinded no TENS groups). Specific comments follow below:

We agree with the reviewer feedback and have changed the analysis as described above

Abstract:
- Line 18: Were characteristics similar across all three groups? Like a global test of difference?

There were no differences between the 3 groups in the demographics reported

- See methods: why were the three groups compared in total as opposed to specific tests: TENS vs. no TENS, TENS vs. placebo TENS which makes more sense especially given the results being very difference in the no TENS group because I assume there will be a difference there.

We have revised the manuscript to create 2 arm comparisons

- The authors report double blind: however, in the no TENS group, how is this blind if there was not a TENS unit.

Revisions have been made, and the new primary outcome (active TENS vs placebo TENS) was blinded

Methods:
- the authors reports that this is a double blind study, however, one arm has no TENS unit placed so the patient cannot be blinded to this intervention. Please amend.

Manuscript has been revised to correct this

- primary outcome: why did the authors specifically chose 60 hours? as opposed to hospital duration or first 24 hours?

The authors chose 60 hours post-operatively for the primary outcome rather than the entire hospital duration to reduce skewing by those discharged much later than anticipated. When our study was designed, most patients stayed at least 60 hours (roughly corresponds to discharge on post-operative day 3), but we accounted for the fact that some patients who delivered in the late afternoon or evening may be discharged in the morning and thus may go home before 72 hours. Furthermore, we knew that
patients in this study would rarely receive additional opioids in the first 24 hours postop due to intrathecal morphine administered at the time of cesarean. Thus, in order to capture the majority of the hospital duration for most patients, we selected a time frame (60 hours) in which we felt most patients would still be in the hospital.

- can the authors clarify that all responses to pain questions, adverse reactions were all collected by telephone visit? Thus, only the primary outcome was ascertained by chart review and the other by telephone?

Yes, all responses to pain questions and adverse reactions were collected by telephone survey. The primary outcome and length of stay were obtained by chart review.

- in the methods, the authors do not describe the rationale behind the no TENS group as opposed to the TENS-placebo group
- To this end, the analysis plan for 3 groups is not well-described. Would recommend two group comparisons as opposed to three group comparisons which may miss two-group differences.

The no TENS group was included as the current standard of care, and also a means to assess for a potential placebo effect of TENS, which, if present, would be clinically valuable information. The manuscript has been revised to 2 group comparisons as described in prior responses.

Results:
-Table 1: The p-values for an RCT for 3 groups are included in the table and should not be presented

Thank you for this feedback. The P-values have been removed

-Line 154-155: the global p-value if that is what is being used, only test for 3-group differences but not the direction of the difference

The manuscript has been revised

- The main limitation of this study is the use of the 3-group comparison across the arms without any rationale for the inclusion of the no TENS group. I think the comparisons that make sense are TENS vs TENS placebo; TENS placebo vs. no TENS or even TENS vs no TENS. It is very hard to interpret the three group results. Less so for the secondary outcomes, but these comparisons should exist for the primary outcomes. Even excluding the no TENS group would make more sense in the interpretation of these findings.

The manuscript has been revised to include 2 group comparisons

Discussion: Provides clear rationale and discussion of the results without overstating findings
- However, while the authors found no difference, we cannot exclude that a difference exists. It could be that the size of the difference was too small to detect, i.e. underpowered or insufficient sample size to detect smaller differences

This limitation has been added to the discussion.
Reviewer #3:

Although caesarean section is the most common surgery in many countries, opioid dependence induced by postoperative analgesia is a less common problem, probably due to limited opioid use for the first 24 hours postoperatively. In view of this discrepancy, it may be useful for the authors to specify the protocol according to which the administration of opioids is extended up to 60 hours postoperatively. In my opinion, the reduced need for opioid administration time and the short duration of hospitalization are secondary results of the study but equal in importance to the main objective, and this aspect was very correctly highlighted.

Trying to reduce pain by electric stimulation is a current method tested in many areas. This original research is a well-designed clinical investigation. Sufficient information had been analyzed, rigorous evaluated, permitting pertinent conclusion. The tables and figures included are appropriate. The references are numerous and fair selected.

The importance of managing postoperative pain remains one of the challenges of all surgical branches, especially in obstetrics given the increasing prevalence of cesarean section. Given the results presented, as well as the idea of offering the possibility of decreasing the dose of opioids used in the management of postoperative pain, it would be interesting to note in the future whether opioid-exposed patients maintain the same results or to what extent they differ.

Thank you very much for this feedback. We agree that follow up work on TENS in those at increased risk for higher opioid requirements is needed, and this is included in the discussion.

STATISTICS EDITOR COMMENTS:

Abstract and lines 129-134: Need to conform to our template for RCTs. The sample size calculation was based on a 25% decrease in mean MME from 6.5 tablets of oxycodone with an estimated SD = 3. Therefore the primary outcome should be formatted in a similar fashion. Comparison of median[IQR] of each cohort is not the same format or stats test. Could then provide the comparison of medians, since the data were non-normally distributed. The sample size/power calculation is based on comparing one group vs another, not for comparison among three groups or between 3 pairings. That would require a stricter alpha value and a larger sample size, due to multiple hypothesis testing.

Using parametric comparisons, mean opioid use (in morphine milligram equivalents) was 21.6 (standard deviation [SD] 35.0) in the active TENS group and 14.2 (SD 20.1) in the placebo group (mean difference 7.4 [95%CI -2.9–17.7]). Thus there was no difference in opioid use presuming a parametric distribution. If these calculations should be included in the manuscript we will add it, currently it is not included to avoid being potentially misleading.

As requested by the reviewers, the primary outcome has been revised to a two arm approach comparing TENS to placebo TENS.
Table 1: Since the groups were randomly allocated, should not present stats results for comparison of baseline variables. Any difference in baseline variables is due to random chance.

P values have been removed from Table 1

Table 2: Need to label this as one of the secondary outcomes.

The table title has been revised

Tables 2, 3, 4: Were pain scores and LOS normally distributed? If not, then should format as median(Range or IQR), rather than as mean ± SD and test non-parametrically.

Revisions have been made to account for nonnormal distribution

Fig 3: Legend should include stats comparing the groups.

Statistical test and P value have been added

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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:

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* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable). - added
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The race variable has been removed from the manuscript as this was not a central component of this study.

6. 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).

Data sharing statement has been added

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Yes

Figure 2: Are items in the exclusion box not mutually exclusive?

A potential participant could have multiple exclusion criteria

Figure 3: okay
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8. 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
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reVITALize definitions have been reviewed. The terms used in the manuscript have been revised to be consistent with this list. The authors confirm all applicable terms in the manuscript are consistent with reVITALize.

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