OBSTETRICS & GYNECOLOGY

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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

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

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Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: May 14, 2021
To: "Christian Haslinger" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-794

RE: Manuscript Number ONG-21-794

Vacuum-induced tamponade for treatment of postpartum hemorrhage – smaller might well be better

Dear Dr. Haslinger:

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 Jun 04, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The use of low-level vacuum (70-90 mm Hg) to contract the myometrium and decrease uterine size is in contrast to traditional mechanical methods used for tamponade, which work by creating outward pressure, causing uterine distention.
1. Why did the authors choose the Bakri balloon for this study? What about a simple Foley catheter? Do they think it can be used as an alternative-This may be more readily available and cheaper as Bakri is still expensive and difficult to use in resource limited settings.
2. How effective was the seal with the non sterile tube attached to the Bakri? Were there any leakage noted anywhere along the circuit?
3. What was the comfort level of the patient? Were they comfortable and what analgesia was used during this procedure?
4. Was there any particular need for US for positioning apart from ensuring the balloon was only in the uterine cavity ? Also could the monitoring be done by simple fundal height measurements rather than US monitoring.
Need for US for monitoring as well as placement can sometimes lead to delays. And though ideal can limit its widespread usage and hence some thoughts on this would be helpful.
5. Why did they choose 50-100 ml?-Any thoughts on this particular volume range?
6. Did the balloon stay in place for all patients? Where there any displacements or expulsions? Did they do any vaginal packing to keep the balloon in place to prevent slippage or expulsion?
7. Where the patients given antibiotics?

8. What is the maximum period the authors feel the the suction can be kept safely on?
9. What about in CS?-Where there any notable differences when used compared to vaginal delivery? When was the suction commenced and what was the methodology employed in these cases?-More info on this will be helpful.
10.I agree with the authors that we need more data on the management of PPH before using the tamponade as well as the time duration before it became effective. Also in those patients where the device failed-what do they think was the reason?
11. Why do the authors think there was a difference in the two time periods-was it only due to the lack of confidence? There was a vast difference in blood loss and other objective measurements as well.
12. Also did the authors note any late recurrences of bleeding after the balloon was removed?
13. What was the observation of the users? Did they find that it was easy to use without any problems?
Overall, the study gives us newer options in vacuum induced tamponade using a existing tool- the Bakri balloon though we would appreciate more information on the above and more studies before wide spread implementation.

Reviewer #2: This is a prospective observational cohort of women with postpartum hemorrhage treated with a vacuum

induced uterine tamponade device.
This is a descriptive study without a comparison/control group. As such, I do not think it a strong enough report for an original research article -- this may be better as a letter.
There is a similar, more robust study published in the same journal in 2020 -- which the authors reference. Aside from also including placental bed bleeding (not just uterine atony) as a criteria, the current study does not add to the existing literature.

Intro
The intro is too wordy.
P. 4 Line 60 Severe maternal morbidity should be defined

Methods
P. 5 Line90 It would be helpful to define the standard first line treatment of PPH at your institution
P. 5 Line 101 It is noted that the vacuum was paused after 1 hour if the "bleeding had stopped". How was this defined? No blood accumulating in the system over that time period? Or was a certain amount considered to be stable?
P. 6 Line 124 -- This should be identified as descriptive statistics

Results
P. 7 Lines 143-149 -- This is an atypical presentation of results and would be better in table format

Reviewer #3: The authors present a cohort study evaluating outcomes in women with postpartum hemorrhage treated with a vacuum-induced modification of an intrauterine tamponade device (Bakri). Their primary outcome was treatment success, defined as avoiding the need for surgical treatment or embolization for persistent postpartum hemorrhage. They found that VIT was more successful in cases of uterine atony compared to placental patholgy and that success was higher in the second half of their 2017-2020 examination period, driven mainly by a reduction in embolization procedures. Some of the early embolizations were later thought to be unnecessary, the result of lack of full confidence in the ability for VIT to provide sufficient PPH treatment.

The study's main value is addition to the existing proof-of-concept literature, further establishing VIT's ability to treat PPH with a good safety profile. A novel addition is that this study included cases of PPH due to placental pathology in addition to uterine atony, where it has been described before.

There seem to be two main limitations to the study. Although the study is described as prospective, there does not appear to be a clear set of inclusion criteria to define the cohort. Patients were identified and included if they received VIT—(line 217) "all women, without exception, who were treated with VIT were consecutively included in this observational study." There is no description of all patients with certain conditions (i.e. PPH) getting VIT for treatment. The cohort may thus be a selection of patients either more likely or less likely to benefit from VIT compared to others with PPH.

In addition, as the authors point out, the study did not include a control group, so while they can describe good outcomes among patients treated with VIT, it is impossible to say if VIT performs any better than other treatments of PPH.

STATISTICAL EDITOR COMMENTS:

Table 1: The sample sizes were 66, 30 and 36, so all %s should be rounded to nearest integer %, not cited to 0.1% precision. Also, since the samples were modest in size, there is little stats power to generalize any NS comparison.

Table 2: Again, need to round %s to nearest integer %, not 0.1% precision. Due to small counts, most of the comparisons require use of Fisher's test, which changes the VIT success rate for atony (16:4::22:0) p-value to 0.04. Likewise for the VIT success for those with placental pathology (4:4::12:2) to p-value = 0.13. So, need to check the calculations. Also, the nominal differences for period A vs B for uterine atony is less than that for the placental pathology group. That is, the statistical difference in one case, but not the other, is a function of the sample sizes, so the conclusion that there is an inherent difference for those subsets is likely not generalizable from these data.

EDITOR COMMENTS:

1. Though we are not interested in your work in the form of an original research report, we would be interested in it if reformatted as a "Procedures and Instruments" manuscript according to our Instructions for Authors (see http://ong.editorialmanager.com).
We would want the conclusions toned down significantly, and decreased emphasis place on outcome differences between the two time periods. Basically, it would take the form of a description of this promising new approach, its rationale, some preliminary data associated with this approach, and a call for further study.

2. 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.

3. 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.

4. 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.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Procedures and Instruments articles should not exceed 2,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

6. 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).
* 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]."

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 limit for Procedures and Instruments is 200 words. Please provide a word count.

8. 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.

Please spell out "VIT" for "vacuum-induced tamponade" throughout the manuscript. The abbreviation may be used in tables and figures.

9. 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%").

10. 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.

11. 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).

12. 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.

Figures 1-3: Please upload as figure files on Editorial Manager.
Figure 4: Please provide a letter of permission for print and online use from C. Haslinger (an email is sufficient).

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 https://wkauthorservices.editage.com/open-access/hybrid.html.

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

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter. 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 Jun 04, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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

Revised Version R1 ONG-21-794
Vacuum-induced tamponade for treatment of postpartum hemorrhage – smaller might well be better

Dear Editors of Obstetrics & Gynecology

Thank you very much for your decision letter.

We deeply appreciate the time and suggestions of the reviewers and editors and would like to respond to their comments.
Thank you for the suggestion to focus more on the method and reduce the comparison of the two observation periods. Having read the statistical editor's comment, we completely agree to remove the p-values in the comparison of the two observational periods and present the results accordingly. We followed your recommendations and changed the article type from "Original Research" to "Procedures and Instruments" with the corresponding format changes, although we regret this because the discussion with strengths and weaknesses as well as the reviewers' comments (regarding the methods) cannot be incorporated as we had wished.
We have read the Instructions for Authors and we agree to publish our point-by-point response letter. The STROBE Guidelines were followed.

The word count of the abstract is 198 words.
The word count of the manuscript is 1989 words (1681 words title page to the end of the manuscript, 308 words tables and figures legends).

I, Christian Haslinger, permit *Obstetrics & Gynecology* to use figure 4 in this manuscript for print and online use. I can send an additional permission email, if necessary, to the editorial office before publication.

We hope that after incorporation of the desired revisions you will find our paper suitable for publication.

Yours sincerely,
Christian Haslinger

COMMENTS FOR THE AUTHOR:

Reviewer # 1

1. Why did the authors choose the Bakri balloon for this study? What about a simple Foley catheter? Do they think it can be used as an alternative-This may be more readily available and cheaper as Bakri is still expensive and difficult to use in resource limited settings.

> This is indeed a very good idea. We used the Bakri balloon because our staff was used to its handling. However, now that proof-of-concept is established, it would be very interesting to test vacuum-induced tamponade with cheaper catheters as well. We added this comment in the discussion section.

2. How effective was the seal with the non sterile tube attached to the Bakri? Were there any leakage noted anywhere along the circuit?

The seal worked out perfectly well, no leakage was reported or documented. We added this information.

3. What was the comfort level of the patient? Were they comfortable and what analgesia was used during this procedure?

No need for additional analgesia. We added this information. The Bakri balloon was inserted as is customary; once the balloon was inserted, no discomfort was reported.

4. Was there any particular need for US for positioning apart from ensuring the balloon was only in the uterine cavity?
Also, could the monitoring be done by simple fundal height measurements rather than US monitoring. Need for US for monitoring as well as placement can sometimes lead to delays. And though ideal can limit its widespread usage and hence some thoughts on this would be helpful.

There is no particular need for US for positioning, the balloon could be inserted without ultrasound guidance. Fundal height measurement seems impractical, as this method seems rather inaccurate and, above all, cannot show if blood is accumulating in the uterine cavity. Hence, wherever possible, the use of US during the treatment of PPH is recommended. At our institution the use of US does not lead to any delay. However, in situations where no US is available, the second best option is to control for fundal height and uterine tonus by manual palpation and check the clinical situation by assessment of vaginal bleeding and vital parameters.

5. Why did they choose 50-100 ml?-Any thoughts on this particular volume range?

We chose 50-100 mL because this amount was considered to be sufficient to achieve and maintain intrauterine vacuum and not too large to risk the opposite effect (the goal is still to reduce uterine size).

6. Did the balloon stay in place for all patients? Were there any displacements or expulsions? Did they do any vaginal packing to keep the balloon in place to prevent slippage or expulsion?

Balloon displacement was observed in women after vaginal delivery with the balloon slipping into the vaginal fornix. No vaginal packing was used; this might be an option to improve balloon placement in the uterus, however might well also be associated with discomfort.

7. Where the patients given antibiotics?

No, antibiotics were given only according to standard management (1g Ceftriaxon in cases of manual removal of the placenta or curettage of retained placental tissue).

8. What is the maximum period the authors feel the suction can be kept safely on?

The treating physician recognizes whether the method is successful or not immediately after initiation of the intrauterine vacuum. If cessation of the suction after >12 hours should lead to re-bleeding, additional pathologies such as retained placental tissue or coagulation disorders should be checked for and treated accordingly.

9. What about in CS?-Were there any notable differences when used compared to vaginal delivery? When was the suction commenced and what was the methodology employed in these cases?-More info on this will be helpful.

The placement of the Bakri balloon takes place as usual: *during* cesarean deliveries “backwards” (placement in the uterine cavity before closure of the uterotomy and from there insertion into the vagina after temporary removal of the valve) and *after* cesarean deliveries transcervical insertion; for the latter case, the continued effect of the spinal anesthesia that was necessary for the cesarean section is needed. Suction was commenced as in vaginal deliveries (immediately after insertion and closure of the uterotomy); some users tended to inflate less volume into the balloon (rather 50 than 100 mL) in order to avoid a tear in the uterotomy.

10.I agree with the authors that we need more data on the management of PPH before using the tamponade as well as the time duration before it became effective. Also in those patients where the device failed-what do they think was the reason?

Firstly, in the first observational period, many women had an embolization of pelvic arteries although the bleeding had stopped after VIT. The treating physicians were happy to have achieved hemorrhage control but did not want to "risk" a re-bleeding and decided to go for embolization in the now clinically stable situation (this was documented accordingly in several cases). So, we classified these cases as "treatment failure" while, in fact, the treatment had worked. With increasing confidence in the method, these "unnecessary" interventions decreased as described in the manuscript. Secondly, as can be seen in Figure 3, treatment failures in the second observational period were found only in women with PPH due to placental pathology (placenta previa or morbidly adherent placenta). This makes sense, as VIT is suitable first of all in women with uterine atony; however, we believe that VIT can support PPH treatment also in women with placental pathology.

11. Why do the authors think there was a difference in the two time periods-was it only due to the lack of confidence? There was a vast difference in blood loss and other objective measurements as well.

With increasing experience and confidence in the new method, physicians tended to use VIT at earlier stages of PPH. Having experienced how fast and simply it works, VIT in the meantime is used immediately in cases of PPH at our institution.

12. Also, did the authors note any late recurrences of bleeding after the balloon was removed?

No.

13. What was the observation of the users? Did they find that it was easy to use without any problems?

A minimal amount of training was necessary: where to insert the connecting tube, how much negative pressure, etc; once explained and with an SOP on the vacuum machine, users found it easy to use.

Overall, the study gives us newer options in vacuum induced tamponade using an existing tool- the Bakri balloon - though we would appreciate more information on the above and more studies before widespread implementation.

Thank you very much for the appreciation; we are agree that we need larger, randomized interventional trials – perhaps, as proposed, with a cheaper (Foley) catheter.

Reviewer # 2

Intro

The intro is too wordy.

P. 4 Line 60 Severe maternal morbidity should be defined

We shortened the introduction. Also due to format restrictions ("procedures and instruments"-articles are limited to 2000 words) we deleted most of the introduction and also omitted the part about maternal morbidity in Scotland.

Methods

P. 5 Line90 It would be helpful to define the standard first line treatment of PPH at your institution

At our institution, first line treatment consists of administration of oxytocin (40 IU within 30 minutes) followed by prostaglandins (sulproston or misoprostol).

P. 5 Line 101 It is noted that the vacuum was paused after 1 hour if the "bleeding had stopped". How was this defined? No blood accumulating in the system over that time period? Or was a certain amount considered to be stable?

"Bleeding stopped" was defined as no further accumulation of blood either in the system or in the uterus – this was added.

P. 6 Line 124 -- This should be identified as descriptive statistics

Done. See also response to statistical editor.

Results
P. 7 Lines 143-149 -- This is an atypical presentation of results and would be better in table format
Done, thank you.

Reviewer # 3

The authors present a cohort study evaluating outcomes in women with postpartum hemorrhage treated with a vacuum-induced modification of an intrauterine tamponade device (Bakri). Their primary outcome was treatment success, defined as avoiding the need for surgical treatment or embolization for persistent postpartum hemorrhage. They found that VIT was more successful in cases of uterine atony compared to placental patholgy and that success was higher in the second half of their 2017-2020 examination period, driven mainly by a reduction in embolization procedures. Some of the early embolizations were later thought to be unnecessary, the result of lack of full confidence in the ability for VIT to provide sufficient PPH treatment.

The study's main value is addition to the existing proof-of-concept literature, further establishing VIT's ability to treat PPH with a good safety profile. A novel addition is that this study included cases of PPH due to placental pathology in addition to uterine atony, where it has been described before.

There seem to be two main limitations to the study. Although the study is described as prospective, there does not appear to be a clear set of inclusion criteria to define the cohort. Patients were identified and included if they received VIT—(line 217) "all women, without exception, who were treated with VIT were consecutively included in this observational study." There is no description of all patients with certain conditions (i.e. PPH) getting VIT for treatment. The cohort may thus be a selection of patients either more likely or less likely to benefit from VIT compared to others with PPH.
We can guarantee that all women who were treated with VIT were included in this study. However, it is correct that this study does not include women who were suffering from PPH and were NOT treated with VIT. This underlines, in fact, the necessity for an adequately powered interventional trial.

In addition, as the authors point out, the study did not include a control group, so while they can describe good outcomes among patients treated with VIT, it is impossible to say if VIT performs any better than other treatments of PPH.
Correct. See above. This is also discussed as much as possible in the discussion section within the length restrictions given.

Statistical Editor comments

Table 1: The sample sizes were 66, 30 and 36, so all %s should be rounded to nearest integer %, not cited to 0.1% precision. Also, since the samples were modest in size, there is little stats power to generalize any NS comparison.
Done.

Table 2: Again, need to round %s to nearest integer %, not 0.1% precision. Due to small counts, most of the comparisons require use of Fisher's test, which changes the VIT success rate for atony (16:4::22:0) p-value to 0.04. Likewise for the VIT success for those with placental pathology (4:4::12:2) to p-value = 0.13. So, need to check the calculations. Also, the nominal differences for period A vs B for uterine atony is less than that for the placental pathology group. That is, the statistical difference in one case, but not the other, is a function of the sample sizes, so the conclusion that there is an inherent difference for those subsets is likely not generalizable from these data.
A Fisher's test was indeed used (though, the numbers were 16:6::22:0 (*not 16:4::22:0*)). However, we thank the statistical editor for this important input. In this situation, the mere calculation of p-values ("because we can") is not appropriate for the sample size and the message we are able to take away from this study. Also, in light of the editor comments, in order to focus on description and decrease emphasis on outcome differences, we decided to remove the p-values and focus, as suggested, on the description.
We thank the (statistical) editors for this significant correction.

EDITOR COMMENTS

1. Though we are not interested in your work in the form of an original research report, we would be interested in it if reformatted as a "Procedures and Instruments" manuscript according to our Instructions for Authors (see http://ong.editorialmanager.com).
We would want the conclusions toned down significantly, and decreased emphasis place on outcome differences between the two time periods. Basically, it would take the form of a description of this promising new approach, its rationale, some preliminary data associated with this approach, and a call for further study.
Done.

2. 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.
Yes, please publish my point-by-point response letter.

3. 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. […]. 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.
STROBE guidelines were followed.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Procedures and Instruments articles should not exceed 2,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.
Done.

6. 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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