OBSTETRICS & GYNECOLOGY

NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- 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: Jul 12, 2019
To: "gabriel levin" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1075

RE: Manuscript Number ONG-19-1075

Subsequent pregnancy outcomes after failed vacuum assisted delivery: A retrospective study

Dear Dr. levin:

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 Aug 02, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Precis - TOLAC after failed vacuum (VAD) is safe and has a high success rate, GDM is a negative predictor

Abstract

- Objective - failed VAED occurs 5-10% of the time and subsequent pregnancies haven't been evaluated - study preferred mode of delivery and success of TOLAC after VAD
- Method - Retrospective cohort - all failed VAD in 10 yrs
- Results - 166 women - 31.9% had elective repeat cesarean (ERCD) and 68% had TOLAC; successful TOLAC occurred in 67.3% with GDM associated with failure
- Apgars were lower if failed TOLAC but there was no increased risk of PPH, anal sphincter injury or uterine rupture
- Conclusions - TOLAC after failed VAD is safe with a high success rate - this helps with counseling

Intro - CD rate is increasing and TOLAC will help decrease this rate, VBAC success is 60-80%, this study evaluates failed VAD in subsequent pregnancies

Materials/Methods - patients - retrospective cohort of failed VAD in 10 yrs

Data Collection - data extracted from electronic medical records

Statistical analysis - index pregnancy, compared with subsequent pregnancies - ERCD vs TOLAC and factors associated with VBAC

Results - 289 women with failed VAD and 166 women with subsequent deliveries

ERCD - 31.9%, 68.1% TOLAC

ERCD - women are older, with higher rate of hypertension, subsequent delivery and lower gestational age

TOLAC - higher rate macrosomia in 1st delivery

113 TOLAC - success 67.3% and 8 with failed VAD (25% risk)

GDM is associated with failed TOLAC

other characteristics didn't differ, Apgars lower if failed TOL

Discussion - RF for failed TOLAC - GDM is a predictor of failure, neonatal birthweight didn't differ and there were no adverse maternal outcomes

TOLAC had 25.8% failed VAD in subsequent pregnancy

limitations - retrospective, not generalizable to centers that allow prolonged pushing

TOLAC after failed VAD is safe with high success but GDM is negative predictor

Comments:

This is an interesting study that provides useful information for counseling patients with failed VAD. It has a higher success than might have been calculated with the VBAC calculator of an AOD c-section.

It is important to know that GDM is a negative predictor to guide counseling. Also, important to see that if VAD has failed before, there is a high chance of subsequent failure.

I think it is crucial to have information on BMI - to see whether differences in maternal BMI affect success of TOLAC. This information should be able to be retrieved from the records and would be valuable to know.

I don't think the difference in age is clinically relevant, but a difference in BMI and the affect on outcome would be highly significant.

Also, why are ERCDs occurring at a lower gestational age - < 39 weeks - are they being delivered before 39 weeks electively?

Lastly, this manuscript needs to be thoroughly proofread.

Reviewer #2: This is stated to be a retrospective cohort study with the two cohorts being women with a history of failed VAVD who underwent trial of labor after cesarean in comparison to women with a history of VAVD who underwent elective repeat cesarean section.

Line 153: definition of failed vacuum extraction is delivery by cesarean delivery after attempted operative delivery (which is an appropriate definition) however the authors do not separate this by reason- there may be multiple variables that cause an abandonment of operative delivery in favor of cesarean section, many of which would impact subsequent discussions on route of delivery and counseling for future pregnancy. The authors' conclusion regarding their findings is that due to relatively high success rates, it is reasonable to discuss feasibility and safety of VTOL after a previous delivery complicated by failed operative delivery.

The initial patient sample size is quite large however the study sample size is much smaller which may not account for catastrophic OB outcomes that are rare.

Reviewer #3: I congratulate the authors for their research in outcomes of those women who had a failed vacuum assisted delivery. Further knowledge of TOL after cesarean is very important for contemporary management of labor.

The manuscript is well written with great clarity and the data is well analyzed.

However, there are areas that require further clarification

The cohort was gathered over a 10- year period during which time labor management may have changed. Does this have any impact upon outcomes in the authors' institution? How does this affect your conclusions?

The sample size is rather small. Does this limit the validity of your conclusions and the generalizability of your conclusions to other practice settings?

Reviewer #4:

General Comments: This is a retrospective cohort study evaluating the outcomes of subsequent deliveries in women who previously experienced a failed vacuum delivery. There does not appear to be much literature, as the authors comment, on this topic, and it is therefore useful in that regard. Their main finding is that among women with failed vacuum delivery, successful trial of labor in subsequent pregnancy is successful in the majority of cases, which is useful information for management of such patients, which as the authors comment, are common. The data are useful, but the manuscript requires significant revision.

Introduction

1. The authors' claim that the primary aim of the study is to determine women's preferences for mode of delivery. However, they assessed only physical outcomes, not patient preference. I would remove this from the aims.

Methods

2. Were there any gestational age limits/exclusions? As operative delivery is relatively contraindicated before 34 weeks as a result of the risk of intraventricular hemorrhage, the authors should comment on this. Additionally, were stillbirths excluded?
3. The authors should describe how charts were identified for inclusion in the study.
4. The authors comment that "use of forceps" (line 143) was a collected data point in the delivery characteristics. Is this meant to imply subsequent use of forceps after failed vacuum?
5. If fetal position/station was recorded prior to use of vacuum in the index pregnancy, this would be very useful information to include in the results.

Results

6. The number of neonates delivered is an odd way of presenting the data - would the total number of deliveries be more appropriate? Is this number representative of the total number of infants delivered in the time frame, or only those who met criteria for inclusion for the study/criteria for operative delivery?

The authors conclude that gestational diabetes is a risk factor for TOLAC failure, but only had 5 total cases in the cohort (both TOLAC and ERCD). This seems insufficient data to make their claim.

The authors comment on maternal morbidity among those who attempted TOLAC, but did not comment on morbidity among those with repeat cesarean. These should be presented also.

Discussion

7. The authors should comment further on how selection and/or information bias could affect the interpretation of their results.

There is a an article in the grey journal regarding subsequent pregnancy outcomes following failed operative delivery. This should be reviewed in the discussion.

Melamed N, Segey M, Hadar E, et al. Outcome of trial of labor after cesarean section in women with past failed operative vaginal delivery. *Am J Obstet Gynecol*. 2013 Jul;209(1):49e1-7.

Tables/Figures

I am unfamiliar with what the authors list as the "push back" delivery method (table 1). This needs further explanation.

If data are skewed, then present median (interquartile) alone. If normal distribution, mean (standard deviation) is sufficient. It is confusing to present medians and means together.

The percentages in figure 1 are confusing - while the percentages add up to 100% in the TOLAC failure box, they do not in the TOLAC success box, though all 76 cases are accounted for. This needs review.

Additionally, there are small typographical errors throughout. The authors need to review in detail. For example:

Line 59: "median inter-delivery interval (missing word) of 28 ..."

Line 104: "TOLAC represents an effective means..."

Line 116: "studies(.) Nevertheless..."

STATISTICAL EDITOR COMMENTS:

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

lines 63-64: The rates of Gest HTN were not significantly different in Table 2.

lines 65-66: The p-value for GDM is incorrect (see next comment) and is NS.

lines 182-183: Need to reconcile with Table 2.

lines 165-167 and Tables 1, 2: Fisher's test was cited in Methods, but not used in several cases where it should have been used. Consequently, the p-values are higher and in some instances, now $p < .05$. For example, Table 2: GDM 0/76 vs 2/37 has $p = 0.11$, not $p = .04$, or 5 min Apgar < 8 0/76 vs 3/37 has $p = .03$, not $.01$. Need to re-do all those comparisons with one or more counts were < 5 .

Table 1: The column of ERCD has $N = 53$, so there is no basis for citing %s to nearest 0.1%, should round to nearest integer %.

Table 2: The columns have total Ns = 76 and 37, so there is no basis for citing %s to nearest 0.1%, should round to nearest integer %.

General: Due to small sample sizes, many of the NS findings may simply be due to lack of stats power.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- can you give use some data about usage instead of just saying "commonly used"? How commonly used? For an Ob Gyn readership, much of your introduction here is pretty general and would be well known to the readers. Could you perhaps make it more focused by having a brief introductory paragraph about the importance of decreasing the cesarean section rate due to increased morbidity, health care costs. Then a comment about vacuum assisted vaginal deliveries--how often done, usually from a low station, failure rate. Factors that lead to the failure rates. Then introduce the gap in knowledge: What about TOLAC after failed Vacuum?

- is it just the paucity of the literature or did you do this because its a relevant clinical question AND there isn't much literature?

- Your affiliations are given in the information about the authors. OK to give the name of the institution. Also, please give the years of study.

- How were patients identified? Do you have an electronic medical record that was in place for all 10 years of your study? Is there an abstracted perinatal data set at your institution? Did you look at paper logs? What ever it is, please describe the source of your data set.

- Can you clarify if all women who met these definitions of prolonged second stage were delivered by operative vaginal delivery or if you allowed women to have even longer second stages. Also, did you do vacuum deliveries in shorter second stages for anything other than non reassuring fetal status? Can you also tell us your forceps assisted delivery rates at your institution? That will provide us a bit of information about your operative vaginal delivery practice there. (Maybe you rarely do vacuums, for instance, but do a lot of forceps) Also, as noted by one reviewer, your table describes sequential forceps--what is that? And what is "pushback" method?

- Do your records allow you to comment on 1. indications for operative vaginal delivery and 2. reasons for failed VE such and 3. Number of pop offs?

- Characteristics of women are described...

- Delete "emergent"--

- In your discussion section, you may want to comment on the EGA for the repeat CS being 38 weeks. Typically, for $> 5-7$ years now at least, in the US there has been a great deal of emphasis on avoiding iatrogenic deliveries prior to 39 weeks for uncomplicated pregnancies--resulting in an EGA of 39 weeks being strongly

preferred for repeat CS deliveries.

- Perhaps more clearly written as: "Of the 113 women undergoing TOLAC in the subsequent pregnancy, 76 (67.3%) successfully delivered vaginally. Of these, 53 (69.7%) delivered spontaneously and there were 23 operative vaginal deliveries (xx with forceps and yy with vacuum)."

- do you have information about when the arrest of labors occurred? First stage? Second stage? Also, please don't use "Fetal distress"--substitute "non reassuring fetal status"

- delete emergent

- Make it clearer please that the 31 denominator here is the 23 successful operative vaginal delivery rates + the 8 failed. Again, please make sure at line 193 that all of the operative vaginal deliveries are clearly Vacuum deliveries and no forceps.

- We prefer to avoid providing p values only unless that is the only appropriate test of significance. Where possible in the abstract AND the text, please provide an effect size (such as an OR or RR) and 95% CI's. Please also provide the absolute numbers.

- One of the major points you make (Abstract, precis and discussion) is about the GDM issue so this definitely needs to be fleshed out w/ data supporting this statement in the text. Also, GDM is not a "predictor" but an association with failed TOLAC.

- Can you present the data in your results section of your institution's overall TOLAC success rate? This success rate of 67.3% is right in the range of what is expected overall for VBAC rates so I'm not sure "Rather high" is correct.

- Perhaps mention the NICHD VBAC calculator here? Substitute "significant" for "vast" on line 222. We don't really need a vast amount of evidence

- This is known as a primacy claim: yours is the first, biggest, best study of its kind. In order to make such a claim, please provide the data bases you have searched (PubMed, Google Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper. Then delete "To the best of our knowledge" as you will have presented the data about the source of that knowledge.

- Your study isn't that much bigger than this one (113 vs 93) so I would tone down the "biggest to date" comments. Your rate of 67% is pretty similar to the 75% rate in the first study as well. Again, all of these are in the commonly reported ranges for successful TOLAC so the conclusion from all 3 of these studies is that the risks of failed TOLAC don't seem to be much different among those who had their first CS after failed vacuum than for general population of TOLACers.

- as you emphasize this here in the discussion, could you add data in your results section to support that, so the reader doesn't have to go to the tables now to see what you are basing this statement on?

- I would delete lines 238-241. This relates to infants of diabetics, not just GDM and the preceding comment about neonatal weight (lines 237-8) is about birthweight among all of your patients, not just those with diabetes. In other words, it seems out of place and doesn't really support your prior comments.

- Have to take this with great caution given very small numbers (8/31) involved. Cannot generalize much here at all. OK to postulate but temper this alot. Also, avoid "Novel"--again a primacy claim.

- This isn't really a major strength, as I've pointed out above, your number of patients isn't that much bigger than the prior study with 93 women. As per the statistical reviewer, the relatively small numbers really limit your ability to generalize conclusions.

- You haven't really assessed "safety"--for instance, you don't have neonatal outcomes beyond Apgar scores. And a lot of maternal complications are relatively rare and would require much larger numbers of patients.

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. 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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

4. Please submit a completed STROBE checklist with your revision.

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>.

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, tables, boxes, figure legends, and print appendixes) but exclude references.

7. 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).

8. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

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

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

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

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

12. Line 223: We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

13. 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.

14. 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 via the Clinical Guidance & Publications page at <https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance>.

15. Figure 1 may be resubmitted as-is.

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

17. If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at <http://ong.editorialmanager.com>. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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 Aug 02, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

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.

Prof. Nancy Chescheir
Editor-in-Chief
Obstetrics and Gynecology
July 2019

RE: Manuscript Number ONG-19-1075

Dear Prof. Chescheir,

We are pleased that the reviewers expressed interest in our manuscript entitled "Subsequent pregnancy outcomes after failed vacuum assisted delivery: A retrospective study". We appreciate the opportunity to submit a revised version that addresses their questions.

Below are our point-by-point responses to the comments raised.

We hope you will find the revised version of our manuscript suitable for publication in *Obstetrics and Gynecology*.

Sincerely

Gabriel Levin MD

REVIEWER COMMENTS:

Reviewer #1:

Comments:

This is an interesting study that provides useful information for counseling patients with failed VAD. It has a higher success than might have been calculated with the VBAC calculator of an AOD c-section. It is important to know that GDM is a negative predictor to guide counseling. Also, important to see that if VAD has failed before, there is a high chance of subsequent failure.

I think it is crucial to have information on BMI - to see whether differences in maternal BMI affect success of TOLAC. This information should be able to be retrieved from the records and would be valuable to know.

I don't think the difference in age is clinically relevant, but a difference in BMI and the affect on outcome would be highly significant.

Answer: We thank the Reviewer for the kind words. Regarding BMI, unfortunately, data regarding maternal anthropometric parameters were incomplete. We agree with the Reviewer that this represents an important caveat and a source of bias. Thus, we mentioned this in the Limitations section (lines 264-265).

Also, why are ERCDs occurring at a lower gestational age - < 39 weeks - are they being delivered before 39 weeks electively?

Answer: This is an important comment. As now described in the Methods section, our hospital is a large tertiary referral center, with over 10,000 deliveries per year. The RCOG and ACOG guidelines recommend scheduling ERCD after 39 completed weeks of gestation due to better neonatal outcomes at late term. Nevertheless, due to our high-delivery volume and the increased morbidity associated with an urgent surgery in case of spontaneous onset of labor, our local hospital policy is to perform ERCD at 38-39 weeks of gestation. In cases of elective CD prior to 39 weeks of gestation, a course of antenatal corticosteroids is administered prior to surgery. This is discussed in detail in the revised Discussion section (lines 243-249).

Lastly, this manuscript needs to be thoroughly proofread.

Answer: Following the Reviwer's comment, the manuscript was edited and proofread by a native English-speaking medical editor.

Reviewer #2:

Line 153: definition of failed vacuum extraction is delivery by cesarean delivery after attempted operative delivery (which is an appropriate definition) however the authors do not separate this by reason- there may be multiple variables that cause an abandonment of operative delivery in favor of cesarean section, many of which would impact subsequent discussions on route of delivery and counseling for future pregnancy.

Answer: The Methods section was revised to clarify this issue. Failed vacuum extraction is defined as no progression of the fetal head despite appropriate traction (as per national committee guidelines) and delivery by cesarean delivery (lines 120-121). We totally agree with the Reviewer that multiple variables may cause abandonment of operative delivery. Since different operators may abandon a vacuum delivery attempt at different stages, we have now added this as a bias to the Limitations section (lines 266-267).

The authors' conclusion regarding their findings is that due to relatively high success rates, it is reasonable to discuss feasibility and safety of VTOL after a previous delivery complicated by failed operative delivery. The initial patient sample size is quite large however the study sample size is much smaller which may not account for catastrophic OB outcomes that are rare.

Answer: Following the Reviewer's comment, the Limitations section was revised to highlight that due to the modest sample size the risk of rare adverse outcomes (e.g. uterine rupture) could not be assessed (lines 271-273).

Reviewer #3:

I congratulate the authors for their research in outcomes of those women who had a failed vacuum assisted delivery. Further knowledge of TOL after cesarean is very important for contemporary management of labor.

The manuscript is well written with great clarity and the data is well analyzed.

However, there are areas that require further clarification

The cohort was gathered over a 10- year period during which time labor management may have changed. Does this have any impact upon outcomes in the authors' institution? How does this affect your conclusions?

Answer: We thank the Reviewer for the kind words. We completely agree with this comment and revised the Limitations section accordingly (lines). As the duration of the study period is 10 years, we cannot exclude the possibility that differences between operators in their clinical practice might have biased our study results. Nevertheless, as now stated in the Methods section, second stage management and indications for operative delivery were uniform throughout the study period (lines 121-123).

The sample size is rather small. Does this limit the validity of your conclusions and the generalizability of your conclusions to other practice settings?

Answer: Following the Reviewer's comment, the Limitations section was revised to highlight that the modest sample size may limit the validity and generalizability of the study findings (lines 271-273)

Reviewer #4:

Introduction

1. The authors' claim that the primary aim of the study is to determine women's preferences for mode of delivery. However, they assessed only physical outcomes, not patient preference. I would remove this from the aims.

Answer: The text was revised accordingly (lines- 24-26, 72-75).

Methods

2. Were there any gestational age limits/exclusions? As operative delivery is relatively contraindicated before 34 weeks as a result of the risk of intraventricular hemorrhage, the authors should comment on this. Additionally, were stillbirths excluded?

Answer: We thank the Reviewer for this comment. We added to the Methods section of the revised version that in our institution, operative delivery is not attempted at <34 weeks of gestation based on our national committee guidelines. In addition, stillbirths were excluded, as is now stated in the Method. We believe the text is now clearer in this regard (lines 90, 123-125).

3. The authors should describe how charts were identified for inclusion in the study.

Answer: As now stated in the Methods section, for the purpose of this study, we abstracted maternal hospital admission records, delivery charts, surgical reports and discharge letters from the electronic medical record databases of the obstetric medicine unit in our medical centers. All women who underwent CD following a failed vacuum extraction were identified from the aforementioned database using ICD-9 diagnosis codes (ICD9 660.7 [0,1,3]). (lines 94-99).

.

4. The authors comment that "use of forceps" (line 143) was a collected data point in the delivery characteristics. Is this meant to imply subsequent use of forceps after failed vacuum?

Answer: Yes. As appears in the Tables and the text, sequential use of forceps implies a trial of forceps delivery after abandonment of a vacuum extraction trial. As described in the Methods section, all women who underwent CD following a failed vacuum extraction were included in the analysis. Based on this case definition, those with subsequent use of forceps after failed vacuum were included only if the forceps attempt was also unsuccessful, followed by CD. Those who were successfully delivered by forceps following vacuum attempt were not included. This is now highlighted in the Methods section (lines 88-89).

5. If fetal position/station was recorded prior to use of vacuum in the index pregnancy, this would be very useful information to include in the results.

Answer: In the revised Methods section it is now mentioned that according to our national committee guidelines, vacuum delivery attempt is discouraged above low-cavity (<2 cm below the ischial spines) (lines 124-125). Fetal head position is not determined routinely prior to vacuum attempt and thus data regarding this variable were incomplete. As we acknowledge that fetal head position may affect study findings, this was mentioned in the Limitations section (lines 262-265).

Results

6. The number of neonates delivered is an odd way of presenting the data - would the total number of deliveries be more appropriate? Is this number representative of the total number of infants delivered in the time frame, or only those who met criteria for inclusion for the study/criteria for operative delivery?

Answer: The Results section was revised accordingly. We believe the revised text is now clearer:

"Of the 92,987 live singleton deliveries during the study period, 6974 (7.5%) involved a VAD attempt. Of these, 289 (4.1%) ended in operative vaginal delivery failure followed by CD. A total of 166 women (57.4%) met the study inclusion criteria and had a subsequent delivery..." (lines 146-149)

The authors conclude that gestational diabetes is a risk factor for TOLAC failure, but only had 5 total cases in the cohort (both TOLAC and ERCD). This seems insufficient data to make their claim.

Answer: We completely agree with the Reviewer. The small sample size renders the statistical p value non-significant, hence only a trend is available. We have changed the Results section accordingly (lines 173-174).

The authors comment on maternal morbidity among those who attempted TOLAC, but did not comment on morbidity among those with repeat cesarean. These should be present ed also.

Answer: While ERCD outcome is an important topic, only 53 women in our cohort chose to undergo ERCD. As there are robust data in the current literature in this regard, and considering the specific aim of the current study, we believe that further investigation of ERCD outcomes is beyond the scope of this study. Moreover, as stated by the other Reviewers, the relatively small sample size would limit the ability to detect differences in infrequent outcomes (lines 271-273).

Discussion

7. The authors should comment further on how selection and/or information bias could affect the interpretation of their results.

Answer: In the Limitation section, it is now mentioned that as patients undergoing TOLAC were younger and with lower rates of gestational hypertensive disorders (i.e. factors known to affect TOLAC success), compared to those electing ERCD, the rate of VBAC might be overestimated, due to a potential selection bias. Furthermore, it is possible that some women who experienced failed VAD delivered elsewhere in the subsequent delivery, exposing the current study to information bias (lines 256-262).

There is an article in the grey journal regarding subsequent pregnancy outcomes following failed operative delivery. This should be reviewed in the discussion.

Melamed N, Segey M, Hadar E, et al. Outcome of trial of labor after cesarean section in women with past failed operative vaginal delivery. Am J Obstet Gynecol. 2013 Jul;209(1):49e1-7.

Answer: This important reference was indeed discussed in the Discussion section (line 208), but the reference itself was mistakenly omitted. This was corrected in the Revised version (reference No. 20).

Tables/Figures

I am unfamiliar with what the authors list as the "push back" delivery method (table 1). This needs further explanation.

Answer: We thank you for this comment. In the Methods section we now elaborated on the "push back" delivery method. This refers to fetal head extraction through the uterine transverse incision by pushing up the fetal head through the vagina by an assistant. (lines 105-107)

If data are skewed, then present median (interquartile) alone. If normal distribution, mean (standard deviation) is sufficient. It is confusing to present medians and means together.

Answer: We thank the Reviewer for this comment. Data were presented as medians and interquartile ranges, and also as means, following consultation with our statistician (Geffen Kleinstern). As the statistical editor did not comment on this issue, we will leave it to the discretion of the reviewers and editors.

The percentages in figure 1 are confusing - while the percentages add up to 100% in the TOLAC failure box, they do not in the TOLAC success box, though all 76 cases are accounted for. This needs review.

Answer:Figure 1 was revised accordingly.

Additionally, there are small typographical errors throughout. The authors need to review in detail. For example:

Line 59: "median inter-delivery interval (missing word) of 28 ..."

Line 104: "TOLAC represents an effective means..."

Line 116: "studies(.) Nevertheless..."

Answer: The text was revised accordingly (lines), and reviewed throughout by a native English-speaking medical editor.

STATISTICAL EDITOR COMMENTS:

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

lines 63-64: The rates of Gest HTN were not significantly different in Table 2.

Answer: Lines 63-64 refer to the women who elected ERCD, for whom data are only presented in Table 1. The differences in rates of gestational HTN between women who

underwent ERCD and TOLAC were statistically significant in both the index and subsequent deliveries, as can be seen in Table 1.

lines 65-66: The p-value for GDM is incorrect (see next comment) and is NS.

Answer: We have now performed Fisher's exact test for all the calculations and revised our results accordingly, and also the Tables.

lines 182-183: Need to reconcile with Table 2.

Answer: Our response to the first comment is also relevant here.

lines 165-167 and Tables 1, 2: Fisher's test was cited in Methods, but not used in several cases where it should have been used. Consequently, the p-values are higher and in some instances, now $p < .05$. For example, Table 2: GDM 0/76 vs 2/37 has $p = 0.11$, not $p = .04$, or 5 min Apgar < 8 0/76 vs 3/37 has $p = .03$, not $.01$. Need to re-do all those comparisons with one or more counts were < 5 .

Answer: We reran Fisher's exact test for all the calculations for which it is appropriate, and revised the results accordingly, also in the Tables.

Table 1: The column of ERCD has $N = 53$, so there is no basis for citing %s to nearest 0.1%, should round to nearest integer %.

Answer: The presentation of the data was revised accordingly, in the Results section, and also in the tables and the figure.

Table 2: The columns have total Ns = 76 and 37, so there is no basis for citing %s to nearest 0.1%, should round to nearest integer %.

Answer: The presentation of the data was revised accordingly, in the Results section, and also in the Tables.

General: Due to small sample sizes, many of the NS findings may simply be due to lack of stats power.

Answer: We completely agree with the Reviewer. The Limitations section was revised to highlight that non-statistically significant findings could be due to the modest sample size and the lack of statistical power for some of the variables (e.g. uterine rupture) (lines 271-273).

EDITOR COMMENTS:

- can you give use some data about usage instead of just saying "commonly used"? How commonly used?

Answer: Vacuum assisted delivery is utilized in about 3% of all deliveries in the United States. This was added to the Introduction section along with an appropriate reference (line 61).

For an Ob Gyn readership, much of your introduction here is pretty general and would be well known to the readers. Could you perhaps make it more focused by having a brief introductory paragraph about the importance of decreasing the cesarean section rate due to increased morbidity, health care costs. Then a comment about vacuum assisted vaginal vaginal deliveries--how often done, usually from a low station, failure rate. Factors that lead to the failure rates. Then introduce the gap in knowledge: What about TOLAC after failed Vacuum?

Answer: The Introduction section was revised accordingly (lines 55-75).

- is it just the paucity of the literature or did you do this because its a relevant clinical question
AND there isn't much literature?

Answer: Thank you. This is correct. We revised the Introduction accordingly, to highlight the clinical importance of the issue addressed (line 72).

- Your affiliations are given in the information about the authors. OK to give the name of the institution. Also, please give the years of study.

Answer: The Methods section was revised to describe our medical center. The years of study are also provided (lines 78-83).

- How were patients identified? Do you have an electronic medical record that was in place for all 10 years of your study? Is there an abstracted perinatal data set at your institution? Did you look at paper logs? What ever it is, please describe the source of your data set.

Answer: As is now stated in the Methods section, for the purpose of this study, we abstracted maternal hospital admission records, delivery charts, surgical reports and discharge letters from the electronic medical record databases of the obstetric medicine unit in our medical center. All the women who underwent CD following a failed vacuum extraction were identified using ICD-9 diagnosis codes (ICD9 660.7 [0,1,3]). (lines 94-99).

- Can you clarify if all women who met these definitions of prolonged second stage were delivered by operative vaginal delivery or if you allowed women to have even longer second stages.

Answer: At our center, not all prolonged second stage deliveries are expedited by operative delivery or a cesarean deliveries. When fetal status is reassuring and progress of labor is

evident, prolonging the second stage is allowed on an individual risk assessment basis and is at the discretion of the senior physician (lines 116-119).

Also, did you do vacuum deliveries in shorter second stages for anything other than non reassuring fetal status?

Answer: Indications for vacuum extraction at our center include prolonged second stage, non-reassuring fetal status and maternal indications (see Methods section and Tables 1 & 2). As appears on Table 1, VAD was performed in one woman with a maternal indication.

Can you also tell us your forceps assisted delivery rates at your institution? That will provide us a bit of information about your operative vaginal delivery practice there. (Maybe you rarely do vacuums, for instance, but do a lot of forceps)

Answer: The forceps delivery rate in our department (and throughout Israel) is extremely low and was 0.1% during the study period. This information is now provided in the text (line 92).

Also, as noted by one reviewer, your table describes sequential forceps--what is that?

Answer: As described in the Methods section, all women who underwent CD following a failed vacuum extraction were included in the analysis. Based on this definition, those with subsequent use of forceps after failed vacuum were included only if the forceps attempt was also unsuccessful, followed by CD. Those who were successfully delivered by forceps following a vacuum attempt, were not included. (lines 8-89)

And what is "pushback" method?

Answer: In the Methods section we now elaborated on the "push back" delivery method, which refers to fetal head extraction through the uterine transverse incision by pushing up the fetal head through the vagina by an assistant. (lines 105-107)

- Do your records allow you to comment on 1. indications for operative vaginal delivery and 2. reasons for failed VE such and 3. Number of pop offs?

Answer: The indications for operative vaginal delivery are described in Table 1 as prolonged second stage (per nulli or parous), non-reassuring fetal status, and maternal indication. Regarding the reasons for failed VAD, the Methods section was revised in order to make this issue more clear- *"Failed vacuum extraction is defined as no progression of the fetal head despite appropriate traction"* (as per national committee guidelines). Unfortunately, data regarding the number of cap dislodgements were incomplete. (lines 119-121)

- Characteristics of women are described...

Answer: The text was revised accordingly. (line 134).

- Delete "emergent"—

Answer: The text was revised accordingly.(line 148)

- In your discussion section, you may want to comment on the EGA for the repeat CS being 38 weeks. Typically, for > 5-7 years now at least, in the US there has been a great deal of emphasis on avoiding iatrogenic deliveries prior to 39 weeks for uncomplicated pregnancies--resulting in an EGA of 39 weeks being strongly preferred for repeat CS deliveries.

Answer: This is an important comment. As now described in the Methods section, our hospital is a large tertiary referral center that serves greater Jerusalem, with over 10,000 deliveries per year. The RCOG and ACOG guidelines recommend scheduling ERCD after 39 completed weeks of gestation due to better neonatal outcomes at late term. Nevertheless, due to our high-delivery volume and the increased morbidity associated with an urgent

surgery in case of spontaneous onset of labor, our local hospital policy is to perform ERCD at 38-39 weeks of gestation. This is discussed in detail in the revised Discussion section (lines 243-249).

- Perhaps more clearly written as: "Of the 113 women undergoing TOLAC in the subsequent pregnancy, 76 (67.3%) successfully delivered vaginally. Of these, 53 (67%) delivered without assistance and 23 (30%) delivered by VAD (none with forceps)"

Answer: The text was revised accordingly (lines 163-165).

- do you have information about when the arrest of labors occurred? First stage? Second stage? Also, please don't use "Fetal distress"--substitute "non reassuring fetal status"

Answer: As now shown in Figure 1 and in the Results section, 12% of arrested labors were in the first stage while the other 88% were at the second stage. We have changed the term "fetal distress" to "non-reassuring fetal status".

- delete emergent

Answer: The text was revised accordingly. (line 167).

- Make it clearer please that the 31 denominator here is the 23 successful operative vaginal delivery rates + the 8 failed. Again, please make sure at line 193 that all of the operative vaginal deliveries are clearly Vacuum deliveries and no forceps.

Answer: The text was revised accordingly (lines 169-172):

"Eight cases in the failed TOLAC group were preceded by a VAD attempt. Thus, the failed VAD rate among the cohort of women who underwent TOLAC was 26%. (Of 31 VAD attempts overall, 23 were successful and 8 unsuccessful)." In line 193 – all deliveries are vacuum extractions.

- We prefer to avoid providing p values only unless that is the only appropriate test of significance. Where possible in the abstract AND the text, please provide an effect size (such as an OR or RR) and 95% CI's. Please also provide the absolute numbers.

Answer: We have corrected the text and abstract accordingly.

- One of the major points you make (Abstract, precis and discussion) is about the GDM issue so this definitely needs to be fleshed out w/ data supporting this statement in the text. Also, GDM is not a "predictor" but an association with failed TOLAC.

Answer: The text was revised accordingly and the percentages, and not only the P values, are now provided. The word "predictor" was omitted and instead the term "association" is now used (lines 173, 214).

- Can you present the data in your results section of your institution's overall TOLAC success rate? This success rate of 67,3% is right in the range of what is expected overall for VBAC rates so I'm not sure "Rather high" is correct.

Answer: It is now mentioned in the text that during the study period, the TOLAC success rate in our institution was 88% (line 92). The term rather high was omitted.

- Perhaps mention the NICHD VBAC calculator here? Substitute "significant" for "vast" on line 222. We don't really need a vast amount of evidence

Answer: The text was revised accordingly and the NICHD VBAC calculator is mentioned. The word "vast" was substituted with "substantial" (line 199, 203).

- This is known as a primacy claim: yours is the first, biggest, best study of its kind. In order to make such a claim, please provide the data bases you have searched (PubMed, Google

Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper. Then delete "To the best of our knowledge" as you will have presented the data about the source of that knowledge.

Answer: We thank you for this comment. This claim was omitted in the Revised version.

- Your study isn't that much bigger than this one (113 vs 93) so I would tone down the "biggest to date" comments. Your rate of 67% is pretty similar to the 75% rate in the first study as well. Again, all of these are in the commonly reported ranges for successful TOLAC so the conclusion from all 3 of these studies is that the risks of failed TOLAC don't seem to be much different among those who had their first CS after failed vacuum than for general population of TOLACers.

Answer: We thank you for this comment. This claim was omitted in the Revised version .

Moreover, neonatal birthweight did not differ in relation to 237
TOLAC success- as you emphasize this here in the discussion, could you add data in your results section to support that, so the reader doesn't have to go to the tables now to see what you are basing this statement on?

Answer: These data were added to the revised Results section (lines 174-177).

- I would delete lines 238-241. This relates to infants of diabetics, not just GDM and the preceding comment about neonatal weight (lines 237-8) is about birthweight among all of your patients, not just those with diabetes. In other words, it seems out of place and doesn't really support your prior comments.

Answer: As suggested, the text referred to was omitted in the revised version.

- Have to take this with great caution given very small numbers (8/31) involved. Cannot

generalize much here at all. OK to postulate but temper this alot. Also, avoid "Novel"--again a primacy claim.

Answer: We agree with the Editor and the text was revised accordingly (lines 237-239).

- This isn't really a major strength, as I've pointed out above, your number of patients isn't that much bigger than the prior study with 93 women. As per the statistical reviewer, the relatively small numbers really limit your ability to generalize conclusions.

Answer: This claim was omitted from the revised version.

In addition, the Limitations section was revised to highlight the disadvantages of the modest sample size (lines 271-273).

- You haven't really assessed "safety"--for instance, you don't have neonatal outcomes beyond Apgar scores. And a lot of maternal complications are relatively rare and would require much larger numbers of patients.

Answer: The Editor is right. The text was revised accordingly throughout the manuscript.

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.

Answer: OPT-IN: Yes, please publish my point-by-point response letter

4. Please submit a completed STROBE checklist with your revision.

Answer: We have submitted a completed STROBE checklist

12. Line 223: We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

Answer: The text was revised accordingly (see prior response to the Editor comments) (lines before line 204 were omitted).)

Date: Aug 07, 2019
To: "gabriel levin" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1075R1

RE: Manuscript Number ONG-19-1075R1

Subsequent pregnancy outcomes after failed vacuum assisted delivery: A retrospective study

Dear Dr. Levin:

Your revised manuscript has been reviewed. There are some additional comments that we need you to address prior to being further discussed by the Editors. Comments from about your revised manuscript are below. You are also receiving an edited version of your submitted revision that contains the comments below and additional edits for your review.

This file is uploaded as an Attachment in your manuscript's submission record. The file name will be "19-1075R1 ms (8-7-19v2)." Please work on your next version using this file.

Your next version will be due in 14 days from today, August 21, 2019. If you need additional time, please contact Randi Zung (rzung@greenjournal.org).

EDITOR'S COMMENTS:

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

2. The following co-authors will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager.

David Mankuta
Aya Lewkowicz

3. Financial Disclosure: After all electronic Copyright Transfer Agreement forms have been completed, please add any additional Financial Disclosures here.

4. Line 40: As noted by the statistical editor and acknowledged by you in your response letter, your study is small enough that percentages should be rounded to the nearest integer. Please correct in your abstract and throughout your paper

5. Line 43: We prefer to avoid providing p values only unless that is the only appropriate test of significance. Where possible in the abstract AND the text, please provide an effect size (such as an OR or RR) and 95% CI's as well as the absolute numbers. For example here, what were the differences in ages and rates of hypertension?

In addition, do you think the differences in age (more < 25 in the CS group but otherwise pretty similar) and Gest Hypertension (small # in both groups) is important to emphasize here? The very wide CI's on the hypertensive rates indicates how unstable this statistic is. Why not say something like "While there were small statistical differences in the pre-delivery characteristics of the two groups, there were not clinically significant differences."

6. Line 132 (Reference 16): Practice Bulletin No. 49 is no longer current ACOG guidance. Please review the updated document, Obstetric Care Consensus No. 1, at <https://www.acog.org/Clinical-Guidance-and-Publications/Obstetric-Care-Consensus-Series-List>. Does the updated document support this statement?

7. Line 169: As noted in the abstract section, for such small n's please limit your percentages to integers. Find to use 7.5% for the almost 7000 women with vacuum delivery attempt, and 4.1% for the 289 who got a CS. but for the small (< 200) numbers, please use integer rules as noted.

8. Line 189: Do you mean "and" here or do you mean "or

9. Line 197-198: We do not allow authors to describe variables or outcomes in terms that imply a difference (such as the terms "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout.

10. Line 215-216 and elsewhere: There was no association with GDM. Please edit here and throughout

11. Line 235: Please round this to a whole integer number. This would be 67%. Please make this change throughout to keep the data presentation consistent

12. Line 240: I'm not convinced you can say "the higher rate" as I bet there isn't really a difference between 75% and 67% when you analyze them statistically. You could say something like, "variations in practice, such as a higher rate of sequential use of forceps after failed vacuum attempt, may underlie minor variations in outcomes of the three studies"

13. Line 244 Please again note that you found NO association with GDM ($p > 0.05$); please edit here. You could say, "The lack of association with gestational diabetes conflicts with reported higher rates of failed trial of labor after cesarean birth in the general population reported by some authors (21, 22)."

14. Line 254: Please expand "ERCP."

15. Line 264: I don't see any data that you have provided that demonstrate improved maternal and perinatal outcomes in women with successful TOLAC vs elective repeat cesarean. You didn't study that and cannot make any concluding remarks about that. You can say the rate of successful TOLAC after prior failed VAD is similar to other TOLAC success rates and that there are not associations you can find that made the rate of failure more or less likely

16. Line 294: As noted before, the age and hypertensive rates are clinically very different. I doubt they contributed selection bias—do you think 27 is that different than 29? As well, I would think your selection bias came from 1/3 of your patients, approximately elected to have an elective cesarean for whatever reason so that the results may be skewed one way or the other

17. References: Please note the edit to reference 16. See query on page 7.

Sincerely,
Nancy C. Chescheir, MD
Editor-in-Chief

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.

Prof. Nancy Chescheir
Editor-in-Chief
Obstetrics and Gynecology
August 2019

RE: Manuscript Number ONG-19-1075R1

Dear Prof. Chescheir,

We are pleased that the Editor-in-Chief has expressed interest in our manuscript entitled " Subsequent Pregnancy Outcomes After Failed Vacuum-Assisted Delivery". We are honored and appreciate the opportunity to submit a newly revised version of our study.

Below are our point-by-point responses to the comments raised.

We hope you will find the revised version of our manuscript suitable for publication in *Obstetrics and Gynecology*.

Sincerely

Gabriel Levin MD

REVIEWER COMMENTS:

EDITOR'S COMMENTS:

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

Answer: we have accepted the changes suggested by track changes and comments.

2. The following co-authors will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager.

David Mankuta

Aya Lewkowicz

Answer: the co-authors have been notified regarding the agreement.

3. Financial Disclosure: After all electronic Copyright Transfer Agreement forms have been completed, please add any additional Financial Disclosures here.

Answer: no additional financial disclosure exist.

4. Line 40: As noted by the statistical editor and acknowledged by you in your response letter, your study is small enough that percentages should be rounded to the nearest integer. Please correct in your abstract and throughout your paper

Answer: we have corrected the data throughout the paper and figure.

5. Line 43: We prefer to avoid providing p values only unless that is the only appropriate test of significance. Where possible in the abstract AND the text, please provide an effect size (such as an OR or RR) and 95% CI's as well as the absolute numbers. For example here, what were the differences in ages and rates of hypertension?

In addition, do you think the differences in age (more < 25 in the CS group but otherwise pretty similar) and Gest Hypertension (small # in both groups) is important to emphasize here? The very wide CI's on the hypertensive rates indicates how unstable this statistic is. Why not say something like "While there were small statistical differences in the pre-delivery characteristics of the two groups, there were not clinically significant differences."

Answer: we have accepted the changes suggested by track changes and comments.

6. Line 132 (Reference 16): Practice Bulletin No. 49 is no longer current ACOG guidance.

Please review the updated document, Obstetric Care Consensus No. 1,

at <https://www.acog.org/Clinical-Guidance-and-Publications/Obstetric-Care-Consensus-Series-List>. Does the updated document support this statement?

Answer: we have changed the reference to the correct one and checked the statement regarding the second stage.

7. Line 169: As noted in the abstract section, for such small n's please limit your percentages to integers. Find to use 7.5% for the almost 7000 women with vacuum delivery attempt, and 4.1% for the 289 who got a CS. but for the small (< 200) numbers, please use integer rules as noted.

Answer: we have made the changes suggested..

8. Line 189: Do you mean "and" here or do you mean "or

Answer: we have changed to "or".

9. Line 197-198: We do not allow authors to describe variables or outcomes in terms that imply a difference (such as the terms "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout.

Answer: we have made the changes suggested throughout the text.

10. Line 215-216 and elsewhere: There was no association with GDM. Please edit here and throughout

Answer: we have edited as suggested throughout the text.

11. Line 235: Please round this to a whole integer number. This would be 67%. Please make this change throughout to keep the data presentation consistent

Answer: we have made the changes suggested throughout the text and proofread for data presentation.

12. Line 240: I'm not convinced you can say "the higher rate" as I bet there isn't really a difference between 75% and 67% when you analyze them statistically. You could say something like, "variations in practice , such a s ahigher rate of sequential use of forceps after failed vacuum attempt, may underlie minor variations in outcomes of the three studies

Answer: we have made the changes suggested.

13. Line 244Please again note that you found NO association with GDM ($p > 0.05$) ; please edit here. You could say, "The lack of association with gestational diabetes conflicts with reported higher rates of failed trial of labor after cesarean birth in the general population reported by some authors (21, 22)."

Answer: we have made the changes suggested.

14. Line 254: Please expand "ERCP."

Answer: we have expanded to elective repeat cesarean section.

15. Line 264: I don't see any data that you have provided that demonstrate improved maternal and perinatal outcomes in women with successful TOLAC vs elective repeat cesarean. You didn't study that and cannot make any concluding remarks about that. You can say the rate of successful TOLAC after prior failed VAD is similar to other TOLAC success rates and that there are not associations you can find that made the rate of failure more or less likely

Answer: we have made the changes suggested.

16. Line 294: As noted before, the age and hypertensive rates are clinically very different. I doubt they contributed selection bias—do you think 27 is that different than 29? As well, I would think your selection bias came from 1/3 of your patients, approximately elected to have an elective cesaeen for what ever reason so that the results may be skewed one way or the other

Answer: we have changed th limitation section accordingly.

17. References: Please note the edit to reference 16. See query on page 7

Answer: we have made the changes suggested..