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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Date: Apr 23, 2021
To: "Carly Dahl" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-306

RE: Manuscript Number ONG-21-306

A Multivariable Predictive Model for Success of External Cephalic Version in a US-Based Population

Dear Dr. Dahl:

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 May 14, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

I want to congratulate the authors on a clearly written manuscript about a common clinical conundrum. I also want to thank them for using inclusive language throughout (e.g. "pregnant individuals"). They created and tested a predictive model for ECV success in a single institution with common use of neuraxial analgesia and near-universal use of uterine relaxants during the procedure.

They found something not unexpected - ECV success is difficult to predict. The best model - produced from BMI, parity, type of fetal malpresentation, and placental location - produced a modest AUC of 0.667 to predict ECV success. As such, the clinical applicability of the calculator is somewhat limited.

Main issues and questions:
1. Please consider moderating claims of very good generalizability in the abstract and discussion. I think the authors have overestimated how well their patient population and procedural practice represent U.S. Aspects that limit generalizability are: (1) single institution study, (2) very common use of neuraxial analgesia, (3) near universal use of uterine relaxants, (4) predominantly white population, (5) relatively low BMI population by U.S. standards.
2. It is not clear to me why neuraxial analgesia was not considered in the prediction model. Neuraxial is associated with success in other studies and is an important component of patient counseling in discussions of ECV. In this cohort, neuraxial was not used in 17%, suggesting that it could be assessed for its predictive ability in the model. Please consider including this or describe a strong rationale for its exclusion.
3. Consider presenting the ROC curves and AUC for all models in a supplementary table. I imagine most of them appear similar, which would be important to know when making decisions about the clinical utility of these results.
4. Would the authors consider reporting more data to demonstrate the clinical utility of this test? Clinicians will wonder: what sorts of values will the model produce in my patients? Among those with successful ECV, what were the predicted values (range and distribution)? Among those with unsuccessful ECV, what were the predicted values (range and distribution)? Were these distributions highly overlapping? In short, the authors make a pitch that the helpful product of this study was the calculator. As a clinician, I would want to see what values the calculator produced in the testing cohort.

Line-by-line comments and questions
5. Abstract, Objective, Line 48. Consider rewording "U.S.-based population." To the reader this implies, incorrectly I think, that the patient population is representative of the United States.
6. Methods, Line 129. I think the categorization of amniotic fluid volume into oligo, poly, and normal is unhelpful. For various reasons, the authors had too few patients in the oligo and poly groups to include in the predictive model. But

amniotic fluid differs substantially in the normal group and seems to matter clinically - would the authors consider predictive modeling that includes AFI or DVP instead?
7. Results. Can the authors clarify which results come from the training cohort versus the testing cohort? This was unclear to me in the results.
8. Results, Line 180-181. Please clarify what is meant, specifically, by "no systemic pattern of ECV outcomes of first and second attempts."
9. Methods and Discussion and Figure 2. What defines the model as having "good calibration" (Figure 2) or "close adherence between predicted and observed"?. Can the authors explain this concept better? Is there a test for "good calibration" vs "bad calibration"?
10. Similarly, in Figure 2, can the authors guide the reader a bit more? Is predicted value the result from the model of the training cohort, and observed average the success rate in the testing cohort? What is "reference"?
11. Discussion, lines 218 - 227. A more thorough discussion of how the results of this predictive model compare to other predictive models is needed, in my opinion. The authors describe limitations of previous studies, with a focus on their data being from international sources, but how did the results differ from this study? Do results of this study harmonize with or depart from previous studies?

Reviewer #2:

Comments to the author:

The authors present a large retrospective study looking at variables that impacted the success of external cephalic version using univariant and multivariant regression. These results were than fitted using receiver operator characteristic curves (AUC) for best discriminatory capacity and development of a ECV success calculator. The concept is interesting; however, the associated variables are well reported in the literature. Unlike VBAC calculator, where risks of failure can increase morbidity, the implications of failure for ECV are relatively insignificant.

Abstract:

Line 47-48 The title is a bit misleading. ECV in a US population implies a multi-institutional generalizable study. This was done at a single institution.

Line 69-71 Given the overall low success rate 40% how exactly would the calculator be used for patient counseling? There is some interesting data from a cost-effective health care perspective using neuraxial blockage showing cost effectiveness around 32%. BMC Pregnancy Childbirth 2010; 10, 3 (Cost Effectiveness Analysis). Was there standardization of how the ECV was done related to technique, tocolysis and use of neuraxial block?

Introduction:

Overall this a great review of the existing literature and relevant studies.

Line 96-101 Explain more about the existing calculators and precisely what the differences are in both BMI and technique. This will make a stronger argument for the objectives of this study being done in a US population. The reader needs a sense of how different these really are.

What literature searches were done to claim primacy for your report?

Methods:

Line 115 I don't know how common patients presented with repeat breech during this study, I assume very few, but not sure why only the first was included vs. Two separate encounters. It probably does not make much of difference for your n.

Line 133-139 How often was there neither EFW at the time of ECV or 2 weeks prior? Was the estimated calculation using birth weight taking account whether the patient had DM or GDM?

Line 140-143 What was typical combined use of tocolysis and epidural? 70%, 100% and was this confirmed in the MR? This may also have changed over the time period of the study 2006-2016. I do see this later in line 184-185 however it does not describe by time periods.

How many attempts were tried on average between the 2 groups? Specify more about the technique of frontward vs. Backward roll or both. There may be selection bias for those with previously known risk factors for failure not trying as hard.

Line 166-169 I appreciate the sensitivity of not using race/ethnicity in the calculator? It is helpful to report however given objectives of generalizability within a US population.

Results:

Line 176 What proportion of all breech presentations were scheduled for ECV. The way this line reads with only 28 declined that amounts to 97.6% acceptance for ECV. How many patients total at your institution had declined prior to scheduling?

Line 193 Not sure if carrying out EFW OR to 1.0004 is consistent with other OR reporting. This would otherwise be 1.00 and NS. Defer to statistical editors.

Table 1

Is there a breakdown of breech by complete vs frank?

Is there data on outcomes related to overall cesarean section rates and morbidity?

Is there a way to also look at regional anesthesia on this table to see if there is any difference in success in your study population? If so this may need to be used for adjustment on table 2.

The calculator was interested to plug in numbers. Consistent with the greatest adjusted OR type of breech was most impactful.

Discussion:

Line 239-240 The AUC results are limiting. I think the calculator may be better used for cost effective analysis like use of regional block and ECV at 37 vs. 39 wks. This may enable counseling on timing. ie if low predicted success rate at 37 wks the patient is more likely than not to have another epidural 39 wks with scheduled cesarean section vs. Attempting ECV at 39 wks and go straight to cesarean if unsuccessful.

Line 259-261 This is a good point regarding success threshold and no increased morbidity that distinguishes the ECV calculator from how the VBAC calculators have historically been used.

Other limitations and some of the questions listed in this review are adequately addressed.

Reviewer #3:

Thank you for the opportunity to review the manuscript by Dahl, et al. entitled "A Multivariable Predictive Model for Success of External Cephalic Version in a US-Based Population." This manuscript is well-written, and the methodologies are sound. I also think that this manuscript is likely to be of interest to practicing obstetricians. I have only a few minor comments:

1. The patient population utilized for this manuscript comes from a single, large academic center. The authors do a good job of addressing this issue throughout the manuscript. Lines 228-230 note that the model is reflective of common procedural techniques of ECV in the US. I might add that these results are mainly generalizable to women who undergo uterine relaxation and regional anesthesia. There are still a fair number of providers who do not utilize regional anesthesia, and I am not certain whether this model would perform the same under these circumstances.
2. The authors did not find a difference in gestation age at the time of procedure between groups. It appears that the vast majority of ECV attempts were performed at 37 weeks. It may also be helpful to comment that these results are most applicable in women who are undergoing version at 37 weeks?
3. Table 2 under "predictors" lists placenta. It would be helpful if the authors specified that this refers to an anterior placenta.
4. The authors might consider adding some clinical scenarios to the manuscript to highlight its utility. As an example, they might say describe that a nulliparous patient with a BMI of XX, and anterior placenta, and transverse presentation had an XX likelihood of success in clinic practice and XX likelihood of success based on the model.
5. The discussion is very well-done. It is balanced with a nuanced discussion of the strengths and limitations of these models.

STATISTICAL EDITOR COMMENTS:

Table 1: The sample sizes are all in the 100s, not 1,000s, so the n(%) should be rounded to nearest 0.1%, not cited to 0.01% (i.e., 1 part per 10,000) precision.

Table 2: Although it is well explained in the main text, should elaborate on the predictors in the Table itself or in its footnote for the reader. That is, parity is a binary with nulliparous as the referent, placenta is also a binary and refers to anterior placenta vs any other and position refers to transverse/oblique position.

Fig 1: Suggest pointing out to readers that the AUC is equivalent to the C-statistic, for those who are more familiar with that terminology.

Fig 2: Rather than the format used for the calibration curve, should adhere to the format shown in (fig 8) of "Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD): Explanation and Elaboration" by K.G.M. Moons, D.G. Altman, J.B. Reitsma, J.P.A. Ionnidis, P. Macaskill, E.W. Steyerberg, A.J. Vickers, D. F. Ransohoff and G. S. Collins, Annals of Internal Medicine 2015:162:W1-W73. This figure allows the reader to see the relationship of observed vs predicted probabilities along the spectrum of probabilities from the data, along with confidence intervals for those prediction estimates (at each decile). Should show the results for deciles of the score for the Authors data set. The advantage to this level of detail is that it would convey to the reader the strength of association at various model scores, along with their relative uncertainty, reflecting how many data were available at various cut-points.

line 205: There are two issues with the on line calculator. First, its output is a point estimate of probability of success to the nearest 0.01%. That level of precision is far beyond the precision that can be extrapolated from these data. Furthermore, it gives the reader no sense of the variability of the point estimate. Changing Fig 2 and including reference to the decile (and its CI) would be more informative for the user and would give a better sense not only of its utility, but its limitations.

EDITORIAL OFFICE COMMENTS:

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

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

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research

instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

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: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

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 Original Research articles is 300 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.

9. 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.

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

11. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

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

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

15. Figures 1-2: Please upload as figure files on Editorial Manager.

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

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

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

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

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

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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 May 14, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Torri D. Metz, MD
Associate Editor, Obstetrics

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

Carly Morgan Dahl
Northwestern University
Department of Obstetrics and Gynecology
[redacted]

May 14th, 2021

Dear Editors,

Thank you for the opportunity to revise our manuscript entitled “A Multivariable Predictive Model for Success of External Cephalic Version” for review and reconsideration of publication as Original Research in *Obstetrics & Gynecology*.

We greatly appreciate the thoughtful comments by the reviewers and believe the revisions have improved our manuscript. Responses to the reviewers and editors are included below. We thank you for your consideration of our revised manuscript for publication. Please feel free to contact me directly with any questions or comments. We look forward to hearing your response.

Sincerely,

Carly Dahl, MD

REVIEWER COMMENTS:

Reviewer #1:

I want to congratulate the authors on a clearly written manuscript about a common clinical conundrum. I also want to thank them for using inclusive language throughout (e.g. "pregnant individuals"). They created and tested a predictive model for ECV success in a single institution with common use of neuraxial analgesia and near-universal use of uterine relaxants during the procedure.

They found something not unexpected - ECV success is difficult to predict. The best model - produced from BMI, parity, type of fetal malpresentation, and placental location - produced a modest AUC of 0.667 to predict ECV success. As such, the clinical applicability of the calculator is somewhat limited.

Thank you for your comments and summary. The clinical utility of this model is primarily to aid healthcare professionals and patients in shared decision making about undergoing an ECV. Thus, it is the calibration curve, rather than the AUC, that provides the most insight into the potential clinical usefulness of the model. A detailed discussion about the use of AUC and calibration curves with respect to predictive models is provided in the discussion with appropriate references (specifically Van Calster et al 2015, Van Calster et al 2019, and Steyerberg et al 2010; Page 14, Lines 282-298).

Main issues and questions:
1. Please consider moderating claims of very good generalizability in the abstract and discussion. I think the authors have overestimated how well their patient population and procedural practice represent U.S. Aspects that limit generalizability are: (1) single institution study, (2) very common use of neuraxial analgesia, (3) near universal use of uterine relaxants, (4) predominantly white population, (5) relatively low BMI population by U.S. standards.

Thank you for these comments. The authors agree that generalizability is impacted by the study population originating from a single institution with common use of neuraxial analgesia and uterine relaxation. These points have been addressed in the limitations (Page 15, Lines 313-315). There is no claim of generalizability in the abstract. While the population is predominantly White, and the BMI may be lower than the general US population, this does not inherently limit generalizability, which should only be impaired if individuals with particular characteristics were not included at all or only to a very small degree, or if the marginal associations were different (e.g. at different BMI). Given that we had a relatively large and diverse population, did not exclude individuals with certain characteristics (e.g., obesity), and did not find nonlinear associations, we do not believe that generalizability is a major issue. In other words, populations do not need to be identical in all ways (e.g. identical means or proportions) in order for generalizability to be maintained (Collins et al NEJM 2020)

2. It is not clear to me why neuraxial analgesia was not considered in the prediction model. Neuraxial is associated with success in other studies and is an important component of patient

counseling in discussions of ECV. In this cohort, neuraxial was not used in 17%, suggesting that it could be assessed for its predictive ability in the model. Please consider including this or describe a strong rationale for its exclusion.

Thank you for this comment. While the authors agree that neuraxial analgesia is associated with success of ECV, we consider the use of analgesia to be a procedural technique that is modifiable and related to provision of care as well as an institutional practice pattern, rather than a non-modifiable patient characteristic. As our goal was to assess the patient factors associated with ECV success, we did not analyze procedural techniques such as uterine relaxation or use of neuraxial analgesia in our predictive model. This rationale is now explained in the methods (Page 8-9, Lines 150-157).

3. Consider presenting the ROC curves and AUC for all models in a supplementary table. I imagine most of them appear similar, which would be important to know when making decisions about the clinical utility of these results.

Thank you for this suggestion. After considering it, the authors were concerned that the additional information would not add significant value to the manuscript and may in fact be overwhelming to the reader. If requested by the Editors as a desired revision, however, we can certainly list these values in a supplemental table.

4. Would the authors consider reporting more data to demonstrate the clinical utility of this test? Clinicians will wonder: what sorts of values will the model produce in my patients? Among those with successful ECV, what were the predicted values (range and distribution)? Among those with unsuccessful ECV, what were the predicted values (range and distribution)? Were these distributions highly overlapping? In short, the authors make a pitch that the helpful product of this study was the calculator. As a clinician, I would want to see what values the calculator produced in the testing cohort.

Thank you for this comment. The calculator in an interactive format was created so that clinicians could better understand the values that the model would produce. The predicted ranges and distributions for ECV success are available in the calibration curve, which has been modified to include the above information (Figure 2). Additionally, the interactive calculator has been modified to include the 95% confidence interval for each output.

Line-by-line comments and questions

5. Abstract, Objective, Line 48. Consider rewording "U.S.-based population." To the reader this implies, incorrectly I think, that the patient population is representative of the United States.

Thank you for this comment. The use of "US-based population" was used to differentiate that this is a contemporary predictive model, that unlike the majority of others, focuses on a population within the US. However, for the reasons addressed, this description has been removed from the title and abstract.

6. Methods, Line 129. I think the categorization of amniotic fluid volume into oligo, poly, and normal is unhelpful. For various reasons, the authors had too few patients in the oligo and poly

groups to include in the predictive model. But amniotic fluid differs substantially in the normal group and seems to matter clinically - would the authors consider predictive modeling that includes AFI or DVP instead?

Thank you for this recommendation. While the authors agree that adding amniotic fluid volume as a continuous variable might add clinical utility to the predictive model if significant associations were identified, our data are limited by the frequency of missing data with respect to exact fluid volume measurements and would require a level of imputation that would render the outcome less clinically meaningful. This has been addressed as a limitation in the manuscript (Page 16, Lines 330-331).

7. Results. Can the authors clarify which results come from the training cohort versus the testing cohort? This was unclear to me in the results.

The original dataset was resampled using bootstrapping. The bootstrapped dataset was divided into a training dataset and a testing dataset. The training dataset was used to construct logistic regression models which were used to create the model. The testing dataset was used to assess the accuracy and the AUC. Thus, the results are dependent on both the training and the testing datasets. This has been further clarified in the methods (Page 9, Lines 174-175).

8. Results, Line 180-181. Please clarify what is meant, specifically, by "no systemic pattern of ECV outcomes of first and second attempts."

Thank you for this comment. This description was meant to clarify that for women who had multiple ECVs within the same pregnancy, that there was not a pattern for which excluding the patients could skew the results. For example, not every patient had a failed first attempt followed by a successful second attempt at a later gestational age for which the overall results would be impacted by excluding this cohort. As this was unclear, has a very small sample size unlike to impact the results, and is more likely to create confusion for the reader, it was removed from the manuscript to improve the clarity of the results (Page 11, Line 207).

9. Methods and Discussion and Figure 2. What defines the model as having "good calibration" (Figure 2) or "close adherence between predicted and observed"?. Can the authors explain this concept better? Is there a test for "good calibration" vs "bad calibration"?

The basis of the calibration curve is that the X axis is the predicted outcome and the Y axis is the observed outcome. The line of best fit (the black line) demonstrates perfect calibration. This would mean that the observed outcome is always equal to the predicted outcome. A perfect calibration curve would be superimposed on the black line (e.g. the "reference"). Thus, models with good calibration have observed outcomes that are near the predicted outcome throughout the range of results. This has been described in detail the methods in the manuscript (Page 10, Lines 179-185).

10. Similarly, in Figure 2, can the authors guide the reader a bit more? Is predicted value the

result from the model of the training cohort, and observed average the success rate in the testing cohort? What is "reference"?

Thank you for this comment. See above answers to #9 for additional clarification. The training dataset was used to create the logistic regression models (e.g. the predicted outcomes) and the testing dataset was used to test the AUC and accuracy of the models (e.g. the observed outcomes). The reference is "perfect calibration" where the predicted outcome is always equal to the observed outcome. This is also further clarified in the methods (Page 10, Lines 179-185).

11. Discussion, lines 218 - 227. A more thorough discussion of how the results of this predictive model compare to other predictive models is needed, in my opinion. The authors describe limitations of previous studies, with a focus on their data being from international sources, but how did the results differ from this study? Do results of this study harmonize with or depart from previous studies?

Thank you for this comment. This has been expanded upon in the discussion (Page 13, Lines 274-280).

Reviewer #2:

Comments to the author:

The authors present a large retrospective study looking at variables that impacted the success of external cephalic version using univariant and multivariant regression. These results were than fitted using receiver operator characteristic curves (AUC) for best discriminatory capacity and development of a ECV success calculator. The concept is interesting; however, the associated variables are well reported in the literature. Unlike VBAC calculator, where risks of failure can increase morbidity, the implications of failure for ECV are relatively insignificant.

Abstract:

Line 47-48 The title is a bit misleading. ECV in a US population implies a multi-institutional generalizable study. This was done at a single institution.

Thank you for this comment. The authors agree that the implication of indicating a "US population" incorrectly and unintentionally implies that this was done at multiple institutions. This language has been modified in the title and abstract, as well as throughout the manuscript.

Line 69-71 Given the overall low success rate 40% how exactly would the calculator be used for patient counseling? There is some interesting data from a cost-effective health care perspective using neuraxial blockage showing cost effectiveness around 32%. BMC Pregnancy Childbirth 2010; 10, 3 (Cost Effectiveness Analysis). Was there standardization of how the ECV was done related to technique, tocolysis and use of neuraxial block?

As mentioned in the discussion, the authors do not think that there is a threshold for predicted success for which an ECV should not be offered (Page 15, lines 306-308), as this decision should be guided by the patient's own preferences and values. The authors anticipate the prediction model will be used for shared decision making with the patient to provide additional information and to create expectations for the predicted success of the ECV, understanding ECV success is a dichotomous outcome. There was no standardization of ECV technique, although as indicated in the methods (Page 9, Lines 158-164), it is common institutional practice at our practice site to use both a tocolytic agent and neuraxial analgesia. There was not standardization of the number of attempts, although it is typical practice to perform 3 attempts including both a forward and backward roll. We have included this additional information in the discussion (Page 16, Lines 337-342). The use of uterine relaxation was fairly universal, however there was a proportion of participants (~15%) who did not use neuraxial analgesia.

Introduction:

Overall this a great review of the existing literature and relevant studies.

Line 96-101 Explain more about the existing calculators and precisely what the differences are in both BMI and technique. This will make a stronger argument for the objectives of this study being done in a US population. The reader needs a sense of how different these really are.

Thank you for this comment. A more detailed comparison of our model compared to existing models is now included in the discussion (Page 13, Lines 274-280).

What literature searches were done to claim primacy for your report?

Language regarding claims of primacy have been removed from the manuscript.

Methods:

Line 115 I don't know how common patients presented with repeat breech during this study, I assume very few, but not sure why only the first was included vs. Two separate encounters. It probably does not make much of difference for your n.

Thank you for this comment. Patients infrequently represented with repeat breech position during the same pregnancy (n=19). Patients who had multiple ECVs during the same pregnancy were excluded to avoid the complexity introduced by non-independent data within the study population, and patients who had multiple ECVs in separate pregnancies (n=19) were included for the first pregnancy only for the same reason. This information is detailed in the results (Page 11, Lines 204-205).

Line 133-139 How often was there neither EFW at the time of ECV or 2 weeks prior? Was the estimated calculation using birth weight taking account whether the patient had DM or GDM?

Birthweight was used as a prediction for estimated fetal weight for 34.6% of participants (n=394). The estimated calculation did not take into account patients with DM or GDM, as this possibility has not been shown to substantively alter the error distribution of ultrasound estimation.

Line 140-143 What was typical combined use of tocolysis and epidural? 70%, 100% and was this confirmed in the MR? This may also have changed over the time period of the study 2006-2016. I do see this later in line 184-185 however it does not describe by time periods.

The rate of combined use of a tocolytic agent and epidural was 80.2% (n=913). The use of tocolysis was confirmed either in the medical administration history when available or in the procedure note. This is now included in the results (Page 11, Lines 212-213). Institutional practice did not significantly vary across the study period.

How many attempts were tried on average between the 2 groups? Specify more about the technique of frontward vs. Backward roll or both. There may be selection bias for those with previously known risk factors for failure not trying as hard.

Thank you for this suggestion. Patients were not standardized to a particular number of attempts, although it is typical institutional practice to perform 3 attempts, including a forward and backward roll. The technique of performing the ECV was dependent on the healthcare professional, and considering the number of obstetricians included in the study (at least 50 individual obstetricians), it is unlikely for specific techniques/approaches to ECV to significantly impact our outcome. The mention of selection bias regarding patients with known risk factors cannot be excluded in our retrospective analysis, and the limitations have now been expanded to include this (Page 16, Lines 337-342).

Line 166-169 I appreciate the sensitivity of not using race/ethnicity in the calculator? It is helpful to report however given objectives of generalizability within a US population.

Thank you and we agree. The demographics of our patient population with respect to race and ethnicity are listed in Table 1.

Results:

Line 176 What proportion of all breech presentations were scheduled for ECV. The way this line reads with only 28 declined that amounts to 97.6% acceptance for ECV. How many patients total at your institution had declined prior to scheduling?

The number of breech presentations during this study period for individuals who met the eligible study criteria was 3,992, of whom 1,138 underwent an ECV (28.5%). However, it is unknown which patients of this total cohort were offered an ECV and if there were significant differences between individuals who underwent and did not undergo an ECV. Thus, as we are unable to describe the difference between these populations and who was offered an ECV, this information was not included in the manuscript. That said, we should

note that we do not expect this to alter the predictive capability of the model, as the model applies to those who undergo a ECV, not the population of all individuals who have a breech fetus.

Line 193 Not sure if carrying out EFW OR to 1.0004 is consistent with other OR reporting. This would otherwise be 1.00 and NS. Defer to statistical editors.

Thank you for this comment. The EFW was carried out to this level due to the small unit of change per gram (e.g. the OR is per unit of gram difference in estimated fetal weight); the authors believe is important to include this level of detail as it helps to illustrate that this variable was significant on univariable analysis.

Table 1

Is there a breakdown of breech by complete vs frank?

Data regarding complete and frank breech was not reliably available, thus patients were categorized into breech or oblique/transverse. The limitations of not being able to further describe the fetal position are included in the discussion (Page 16, Lines 329-330).

Is there data on outcomes related to overall cesarean section rates and morbidity?

Data regarding cesarean section rates as well as neonatal morbidity/mortality exist but these and other health outcomes are beyond the scope of this manuscript; we do not believe their inclusion would clarify any aspect of the prediction model, and conversely would make the manuscript have less focus.

Is there a way to also look at regional anesthesia on this table to see if there is any difference in success in your study population? If so this may need to be used for adjustment on table 2.

The authors elected to exclude the use of uterine tocolytic agents and neuraxial analgesia as variables within the predictive model as they are felt to be modifiable procedural techniques that are separate from non-modifiable patient characteristics, thus these were intentionally excluded from the analysis. This rationale is now included in the methods (Pages 8-9, Lines 150-157).

The calculator was interested to plug in numbers. Consistent with the greatest adjusted OR type of breech was most impactful.

Thank you for this comment. The calculator has also been modified to include a 95% confidence interval for each output.

Discussion:

Line 239-240 The AUC results are limiting. I think the calculator may be better used for cost

effective analysis like use of regional block and ECV at 37 vs. 39 wks. This may enable counseling on timing. ie if low predicted success rate at 37 wks the patient is more likely than not to have another epidural 39 wks with scheduled cesarean section vs. Attempting ECV at 39 wks and go straight to cesarean if unsuccessful.

Thank you for this interesting comment. While the AUC is commonly used to evaluate prediction models, the AUC of the model demonstrates its capability to dichotomously classify an outcome as a success or a failure. That our AUC is >0.5 demonstrates that our model predicts clinical outcomes significantly greater than chance. The ability of our model to provide a specific probability of success based on individualized patient characteristics, as would be desired for routine clinical counseling, is showcased by the calibration curve (Figure 2). The reliability of the prediction model to predict an outcome is important as this tool would be used for counseling and decision making – thus the goal is to provide an individualized success score for patients based on their personal characteristics. The patient can then use this predicted success score to determine their desire to ultimately undergo the procedure, as ultimately the outcome of ECV is dichotomously a success or a failure, making the AUC less useful in this scenario. This explanation is also included in the manuscript in the discussion (Page 14, Lines 282-298). The use of the model for a cost-effective analysis regarding neuraxial analgesia at a particular gestational age is very interesting but likely beyond the scope of the current manuscript.

Line 259-261 This is a good point regarding success threshold and no increased morbidity that distinguishes the ECV calculator from how the VBAC calculators have historically been used.

Thank you for this comment.

Other limitations and some of the questions listed in this review are adequately addressed.

Thank you for this comment.

Reviewer #3:

Thank you for the opportunity to review the manuscript by Dahl, et al. entitled "A Multivariable Predictive Model for Success of External Cephalic Version in a US-Based Population." This manuscript is well-written, and the methodologies are sound. I also think that this manuscript is likely to be of interest to practicing obstetricians. I have only a few minor comments:

1. The patient population utilized for this manuscript comes from a single, large academic center. The authors do a good job of addressing this issue throughout the manuscript. Lines 228-230 note that the model is reflective of common procedural techniques of ECV in the US. I might add that these results are mainly generalizable to women who undergo uterine relaxation and regional anesthesia. There are still a fair number of providers who do not utilize regional anesthesia, and I am not certain whether this model would perform the same under these circumstances.

Thank you for this comment and we agree. The generalizability to populations that use neuraxial analgesia and tocolysis has been noted in the limitations of the discussion (Page 15, Lines 313-315).

2. The authors did not find a difference in gestation age at the time of procedure between groups. It appears that the vast majority of ECV attempts were performed at 37 weeks. It may also be helpful to comment that these results are most applicable in women who are undergoing version at 37 weeks?

Thank you for noting this. The gestational age range varies from 34-41 weeks, however as mentioned the vast majority of participants had ECVs between 37-38 weeks. As this variable was not significant and the data include a range of gestational ages, the authors prefer to avoid claims of generalizability regarding particular gestational ages.

3. Table 2 under "predictors" lists placenta. It would be helpful if the authors specified that this refers to an anterior placenta.

Thank you for this comment. This clarification has been updated in Table 2, as well as a clarification of the fetal malpresentation and parity.

4. The authors might consider adding some clinical scenarios to the manuscript to highlight its utility. As an example, they might say describe that a nulliparous patient with a BMI of XX, and anterior placenta, and transverse presentation had an XX likelihood of success in clinic practice and XX likelihood of success based on the model.

Thank you for this suggestion. This has now been added to the manuscript in the results (Page 12, Lines 236-239).

5. The discussion is very well-done. It is balanced with a nuanced discussion of the strengths and limitations of these models.

Thank you for this comment.

STATISTICAL EDITOR COMMENTS:

Table 1: The sample sizes are all in the 100s, not 1,000s, so the n(%) should be rounded to nearest 0.1%, not cited to 0.01% (i.e., 1 part per 10,000) precision.

Thank you for this comment. This has been changed in Table 1.

Table 2: Although it is well explained in the main text, should elaborate on the predictors in the

Table itself or in its footnote for the reader. That is, parity is a binary with nulliparous as the referent, placenta is also a binary and refers to anterior placenta vs any other and position refers to transverse/oblique position.

Thank you for this suggestion. This has been changed in Table 2.

Fig 1: Suggest pointing out to readers that the AUC is equivalent to the C-statistic, for those who are more familiar with that terminology.

Thank you for this comment. This has now been included in the manuscript (Page 9, Line 173).

Fig 2: Rather than the format used for the calibration curve, should adhere to the format shown in (fig 8) of "Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD): Explanation and Elaboration" by K.G.M. Moons, D.G. Altman, J.B. Reitsma, J.P.A. Ionnidis, P. Macaskill, E.W. Steyerberg, A.J. Vickers, D. F. Ransohoff and G. S. Collins, Annals of Internal Medicine 2015:162:W1-W73. This figure allows the reader to see the relationship of observed vs predicted probabilities along the spectrum of probabilities from the data, along with confidence intervals for those prediction estimates (at each decile). Should show the results for deciles of the score for the Authors data set. The advantage to this level of detail is that it would convey to the reader the strength of association at various model scores, along with their relative uncertainty, reflecting how many data were available at various cut-points.

Thank you for this suggestion. Figure 2 has been updated with a modified figure legend.

line 205: There are two issues with the on line calculator. First, its output is a point estimate of probability of success to the nearest 0.01%. That level of precision is far beyond the precision that can be extrapolated from these data. Furthermore, it gives the reader no sense of the variability of the point estimate. Changing Fig 2 and including reference to the decile (and its CI) would be more informative for the user and would give a better sense not only of its utility, but its limitations.

Thank you for these comments. The online calculator has been updated to include the nearest percent. Figure 2 has been updated to reflect confidence intervals. This has also been modified in the online calculator, as well.

EDITORIAL OFFICE COMMENTS:

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

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Disclosures are correctly listed.

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

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

All above points have been addressed in the manuscript.

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://urldefense.com/v3/__https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions__;!!Dq0X2DkFhyF93HkjWTBQKhk!H24U_UXZ3fUpTaI37TTDlyEXADPY0mh_XF_Xt35dkzfTFNINTxk6GdBqdM_xMujXKoBmX9zq$ and the gynecology data definitions at https://urldefense.com/v3/__https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions__;!!Dq0X2DkFhyF93HkjWTBQKhk!H24U_UXZ3fUpTaI37TTDlyEXADPY0mh_XF_Xt35dkzfTFNINTxk6GdBqdM_xMujXKtzMP74X$. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Our manuscript adheres to the included definitions.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

Revised edits adhere to the above categories and are listed in the revised manuscript.

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.
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* 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]."

All of the above rules have been followed. There is no manuscript preparation assistance to report and the manuscript was not uploaded to a preprint server prior to submission.

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 Original Research articles is 300 words. Please provide a word count.

The abstract has been modified, is consistent with the manuscript, and follows the word limit which is provided in the title page.

8. Only standard abbreviations and acronyms are allowed. A selected list is available online at https://urldefense.com/v3/__http://edmgr.ovid.com/ong/accounts/abbreviations.pdf__;!!Dq0X2DkFhyF93HkjWTBQKhk!H24U_UXZ3fUpTaI37TTDlyEXADPY0mh_XF_Xt35dkzfTFNINTxk6GdBqdM_xMujXKtQZ7o6U$. 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.

The abbreviations in the manuscript follow the above regulations. The abbreviation "EFW" was used throughout the paper and is not on the list, thus was removed from the manuscript where applicable.

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

This symbol has been removed throughout the text when appropriate.

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If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

This statistical reporting and formatting has been adhered to throughout the manuscript where appropriate.

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Thank you for this comment. We have removed language assuming primacy from the manuscript. When discussing previous ECV prediction models we state that the majority, but not all, of existing models have been performed in international populations. We have modified this language to clarify this.

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: https://urldefense.com/v3/__http://edmgr.ovid.com/ong/accounts/table_checklist.pdf__;!!Dq0X2DkFhyF93HkjWTBQKhk!H24U_UXZ3fUpTaI37TTDlyEXADPY0mh_XF_Xt35dkzfTFNINTxk6GdBqdM_xMujXKtm649qZ$.

Thank you for this comment. The tables have been updated to adhere to the above checklist.

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The references have been updated to be recommended format and all ACOG documents are up to date in the reference list.

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