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

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Questions about these materials may be directed to the Obstetrics & Gynecology editorial office: obgyn@greenjournal.org.
RE: Manuscript Number ONG-22-385

Maternal Outcomes in Subsequent Pregnancies after Classical Cesarean Delivery

Dear Dr. Thompson:

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

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Apr 07, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

ABSTRACT

Please indicate that the definition of SMM is based upon CDC criteria. Perhaps you could mention just a few of the major criteria from the list of 21 to give the reader some framework.

METHODS

Please specify whether the chi square test was corrected versus uncorrected. Given the very large sample size, the uncorrected test is certainly appropriate.

RESULTS

Do you have access to any information that would explain why 31.3% of the patients with a history of prior CCD who were delivered by repeat cesarean had another classical incision. As a general rule, repeating the vertical incision should not be necessary unless the prior vertical incision is disrupted. Certainly, a low transverse incision will heal more readily.

Reviewer #2:

Obstetrics and Gynecology
Manuscript # ONG-22-385

"Maternal outcomes in subsequent pregnancies after classical cesarean delivery"
GENERAL

The submitted manuscript is a retrospective review of patients delivering following either a previous classical or lower uterine transverse cesarean section(s) with respect to maternal outcomes.

1. The manuscript is quite articulate and well-organized.
2. As patients with previous classical cesarean section typically do not undergo a trial of labor, do the authors have any specific information regarding circumstances in which 4.5% of patients (N=1785) apparently did so?
3. Was any consideration given to number of previous cesarean sections?
4. Line 86: Was "previous preterm delivery" considered as a clinical risk factor (as classical cesarean hysterotomy is often related to gestational age at previous delivery)? This also appears to be reflected in the "Prior CCD" group having higher rates of preterm delivery at all gestational ages prior to 37 weeks and (Lines 141-142) in the repeat CCD group.
5. Do the authors have data regarding the incidence of severe maternal morbidity in the "Prior CCD" group who underwent planned repeat cesarean delivery versus those who underwent trial of labor? Is the 5.9% incidence possibly confined to this group?

Reviewer #3:

Green Journal Review

10 - severe maternal morbidity (SMM) - I line 155-157 this is broken down into individual components (table 2) which is very helpful to stratify risk and provide counseling to patients with a prior CCD.

11 - propensity score method - what is this?

17 - 91.3% seems like a very high repeat CD rate

20 - 1.1% vs 0.3% seems like an a rate of uterine rupture consistent with other reported rates

29 - 36 - well done introduction/epidemiology

58 - Good to exclude both CCD and LTCD. What about Mid or high transverse?

146 - How was uterine rupture defined? Was this different than uterine window vs asymptomatic uterine dehiscence noted at the time of surgery vs uterine rupture?

187-194 - The question of clinical utility is the rate of rupture with labor or the rate of rupture based on gestational age. What was the gestational age at the time of diagnosis?

195 - 202 - the rate of rupture after labor is a very helpful statistic with this sizable cohort. I would put the raw number of patients prior to the (%) so we can know how large the sample was in line 195-196.

The strengths of this paper are:
1. Focused clinical question
2. Large sample size
3. Rigorous statistics to have a robust exclusion criteria and matching to avoid confounding
4. Well-written, clear, thoughtful and clinically useful

Weaknesses/limitations: Overall this is a very interesting and helpful paper. Some things can be done to improve the paper:
1. A flowchart of all the patients into each arm CCD vs LTCD and then again into labor vs no labor then uterine rupture vs no rupture and then again into % who have elevated SMM would be very helpful
2. Do you know the rate of fetal injury after uterine rupture? It would be very helpful clinically to be able to say X% of patients w/ a hx of CCD will have a uterine rupture (with and without labor). For example, perhaps 1/100 patients with prior CCD will have a uterine rupture after labor and 1/100 of those infants will have significant neurologic injury. This should be easily captured through matching maternal and newborn records or searching for neurologic injury for newborns on discharge from the hospital.
3. Does not have any comment on prior uterine or uterine surgery - While this is unlikely to be a large number, I would add this as an exclusion criteria
STATISTICS EDITOR COMMENTS:

Lines 122-134, Table 1: Need to state whether the counts were from the NIS or weighted to be representative of the entire US population. Should use a flow diagram to show the crude and weighted counts for the overall data set and key subsets and their outcomes. Since all counts are rounded to either 5 or 0, I suspect that these are all extrapolated by ~ 5x.

Table 2: The ORs appear to be based on the crude counts, rather than weighted, extrapolated counts. I concur with this method.

Figs 1 and 2 are placed after Appendices 1 and 2 in my copy. I assume they are in main text, they should be, esp figure 2. Suggest that Fig 2 legend should include that IPTW method was used, even though it is stated in the Figure itself.

EDITOR COMMENTS:

Please include in your Abstract differential rates of uterine rupture by labor or no labor among women with prior CCD.

EDITORIAL OFFICE COMMENTS:

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

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

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:

* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

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

4. 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.

5. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Methods section of the body text, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

6. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

7. Your study uses ICD-10 data, please make sure you do the following:
   a. State which ICD-10-CM/PCS codes or algorithms were used as Supplemental Digital Content.
   b. Use both the diagnosis and procedure codes.
   c. Verify the selected codes apply for all years of the study.
   d. Conduct sensitivity analyses using definitions based on alternative codes.
   e. For studies incorporating both ICD-9 and ICD-10-CM/PCS codes, the Discussion section should acknowledge there may be disruptions in observed rates related to the coding transition and that coding errors could contribute to limitations of the study. The limitations section should include the implications of using data not created or collected to answer a specific research question, including possible unmeasured confounding, misclassification bias, missing data, and changing participant eligibility over time.
   f. The journal does not require that the title include the name of the database, geographic region or dates, or use of...
database linkage, but this data should be included in the abstract.
g. Include RECORD items 6.3 and 7.1, which relate to transparency about which codes, validation method, and linkage were used to identify participants and variables collected.

8. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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

10. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* 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]."

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

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words; Reviews is 300 words; Case Reports is 125 words; Current Commentary articles is 250 words; Executive Summaries, Consensus Statements, and Guidelines are 250 words; Clinical Practice and Quality is 300 words; Procedures and Instruments is 200 words. Please provide a word count.

12. 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.
13. 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.

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

15. 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").

16. 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.

17. 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 references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn’t listed as "Withdrawn," it’s still a current document.

If the reference you are citing has been updated and 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.

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

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.
Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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

* A confirmation that you have read the Instructions for Authors (http://edm.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 Apr 07, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD
Deputy Editor, Obstetrics

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

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

RE: Manuscript Number ONG-22-385, Maternal Outcomes in Subsequent Pregnancies after Classical Cesarean Delivery

We thank the reviewers and Editors for the thoughtful comments and for the opportunity to revise our manuscript. We have carefully revised our manuscript to address these comments and included our point-by-point responses below. For ease of presentation, reviewers’ comments are shown verbatim in italicized font and our responses are shown in non-italicized font. Because the track-changes function may affect line numbers, we have submitted our revised manuscript in a track-changes version, as well as a clean version. Line numbers referenced in our responses refer to those in the clean version manuscript.

Please let us know if you need any clarification about these responses. We look forward to your further correspondence.

Sincerely,

Beatrix Thompson, corresponding author

Reviewer #1:

ABSTRACT

Please indicate that the definition of SMM is based upon CDC criteria. Perhaps you could mention just a few of the major criteria from the list of 21 to give the reader some framework.

We appreciate this comment. As requested, we added language to the abstract indicating that the definition of severe maternal morbidity (SMM) is based upon the Centers for Disease Control and Prevention (CDC) criteria. Due to space limitations, we cannot include a detailed list of example morbidities in the abstract. However, we do provide details about all 21 morbidities that compose the composite SMM measure in our Methods section.

Specifically, our revised Abstract states the following in lines 8-9:

“Outcome measures included mode of delivery, uterine rupture, and severe maternal morbidity (SMM) as defined by the Centers for Disease Control and Prevention.”

Our Methods section states the following in lines 78-88:

“The CDC SMM composite indicator measured whether a patient experienced any one of the following twenty-one conditions/procedures based on ICD-10 diagnosis and procedure codes: acute myocardial infection, aneurysm, acute renal failure, adult respiratory distress syndrome, amniotic fluid embolism, cardiac arrest/ventricular fibrillation, conversion of cardiac rhythm, disseminated intravascular coagulation,
eclampsia, heart failure/arrest during surgery or procedure, puerperal cerebrovascular disorders, pulmonary edema/acute heart failure, severe anesthesia complications, sepsis, shock, sickle cell disease with crisis, air and thrombotic embolism, blood products transfusion, hysterectomy, temporary tracheostomy, or ventilation. Blood transfusion was the predominant morbidity, so we also measured an alternative composite indicator of SMM without transfusion. For individual SMM items, we only reported the most prevalent ones to protect patient confidentiality and avoid reporting small cells.”

METHODS

Please specify whether the chi square test was corrected versus uncorrected. Given the very large sample size, the uncorrected test is certainly appropriate.

We appreciate this opportunity to clarify the chi square test used in our analysis. As the reviewer noted, because our sample size is large, continuity correction will have minimal impact on our results. Therefore, we have chosen not to use continuity correction when performing chi square test. However, because the National Inpatient Sample (NIS) data used a complex sample design, we applied the Rao-Scott correction to the chi square test to account for the design effect.

We have revised the relevant sentence in our Methods section to clarify this point. Specifically, we stated the following in lines 108-110:

“We compared clinical and non-clinical characteristics of patients who had prior CCD versus prior LTCD using chi-square test with Rao-Scott correction to account for the complex sample design of NIS.”

RESULTS

Do you have access to any information that would explain why 31.3% of the patients with a history of prior CCD who were delivered by repeat cesarean had another classical incision. As a general rule, repeating the vertical incision should not be necessary unless the prior vertical incision is disrupted. Certainly, a low transverse incision will heal more readily.

We agree that it is important to understand the reasons why these patients underwent repeat classical cesarean delivery (CCD). Unfortunately, we did not have detailed information regarding indications for repeat CCD. We have revised our Discussion section to acknowledge this as a study limitation. Specifically, we stated the following in lines 224-229:

“… clinical information in the NIS database largely depends on ICD-10 diagnosis and procedure codes. … Diagnosis and procedure codes … lacked sufficient granularity for understanding the specific circumstances of labor that might influence clinical decision-making.”
Reviewer #2:

GENERAL

The submitted manuscript is a retrospective review of patients delivering following either a previous classical or lower uterine transverse cesarean section(s) with respect to maternal outcomes.

1. The manuscript is quite articulate and well-organized.

   Thank you.

2. As patients with previous classical cesarean section typically do not undergo a trial of labor, do the authors have any specific information regarding circumstances in which 4.5% of patients (N=1785) apparently did so?

   It is possible that this small proportion of patients presented in spontaneous labor and thus were classified as undergoing a trial of labor. Unfortunately, the clinical information available in our data is largely limited to diagnosis and procedure codes, which lacks granular detail about the exact clinical circumstances for these patients. We have revised our Discussion section to acknowledge this as a study limitation. Specifically, we added the following statement in lines 224-229:

   “… clinical information in the NIS database largely depends on ICD-10 diagnosis and procedure codes. … Diagnosis and procedure codes … lacked sufficient granularity for understanding the specific circumstances of labor that might influence clinical decision-making.”

3. Was any consideration given to number of previous cesarean sections?

   We agree that number of previous cesarean deliveries is an important factor influencing clinical decisions about mode of delivery, as well as maternal outcomes. However, we are unable to measure this important factor due to the availability of information in the NIS database, which is cross-sectional in nature and relies upon ICD-10 diagnosis and procedure codes to identify patients’ clinical characteristics. There currently exist no ICD-10 diagnosis codes that address the number of prior cesarean sections. We have added this as a study limitation in lines 224-229 of the Discussion section. Specifically, we stated:

   “… clinical information in the NIS database largely depends on ICD-10 diagnosis and procedure codes. These codes … do not capture all important clinical factors (such as number of prior cesareans) that may influence maternal outcomes.”

4. Line 86: Was "previous preterm delivery" considered as a clinical risk factor (as classical cesarean hysterotomy is often related to gestational age at previous delivery)? This also appears
to be reflected in the "Prior CCD" group having higher rates of preterm delivery at all gestational ages prior to 37 weeks and (Lines 141-142) in the repeat CCD group.

We appreciate the suggestion and would like to clarify that our analytical approach used a propensity score method which already accounted for differences in gestational age between the prior CCD and prior low transverse cesarean delivery (LTCD) groups. In addition, previous preterm delivery would be highly confounded with our exposure indicator (i.e., prior CCD). Therefore, we have chosen not to add previous preterm delivery as an additional clinical risk factor to our model.

5. Do the authors have data regarding the incidence of severe maternal morbidity in the "Prior CCD" group who underwent planned repeat cesarean delivery versus those who underwent trial of labor? Is the 5.9% incidence possibly confined to this group?

We appreciate the reviewer’s suggestion to check whether most of the SMMs in the “Prior CCD” group occurred among patients who underwent labor. Please note that patients who underwent labor only accounted for a very small proportion (7.0%) of the “Prior CCD” group, and therefore, they are unlikely to contribute to most of the SMM incidences in the “Prior CCD” group. Indeed, among the 1,515 patients in the “Prior CCD” group who experienced SMM, 1,460 (96.4%) underwent planned repeat cesarean delivery.

In addition, we expect there to be substantial confounding between the occurrence of labor and patients’ baseline risk factors, such as underlying medical conditions and placenta accreta and previa. These risk factors would be associated with performing a planned cesarean delivery, as well as with risk of SMM. Therefore, a simple comparison of the raw rate of SMM between patients who labored and those who underwent planned repeat cesarean delivery would be highly confounded, and thus, we have chosen not to report the SMM rates for these two groups separately.

Reviewer #3

10 - severe maternal morbidity (SMM) - I line 155-157 this is broken down into individual components (table 2) which is very helpful to stratify risk and provide counseling to patients with a prior CCD.

Thank you.

11 - propensity score method - what is this?

Propensity score is the probability of a patient being in the “treated” group (i.e., prior CCD group in our study), as opposed to the “control” group (i.e., prior LTCD group in our study), conditional on their observed baseline characteristics (Austin 2011). Inverse probability of treatment weighting (IPTW) used in our analysis is one type of propensity score method. It used the propensity score to help balance the distribution of baseline characteristics between the “treated” and the “control” groups such that observational
(nonrandomized) data can be analyzed in a way that mimics a randomized controlled trial (Austin 2011). We have revised our Methods section in lines 110-114 to help clarify this concept. Specifically, we stated:

“To account for differences in maternal clinical characteristics between these two groups, our assessment of patient outcomes (mode of delivery, uterine rupture, and SMM composite and individual items) used a propensity score method via inverse probability of treatment weighting (IPTW) to help balance baseline characteristics of patients between the prior CCD and prior LTCD groups.”

Reference:


17 - 91.3% seems like a very high repeat CD rate

We appreciate this comment. In response, we closely reviewed the rate of repeat cesarean delivery in our data and noted the following. In the 2016-2019 NIS data, there were a total of 2,480,508 singleton live births delivered at ≥24 weeks that had a prior cesarean delivery and were not transferred-in from another facility. The rate of repeat cesarean delivery in this overall sample was 87.5%, which was very similar to the national data reported by the CDC (Osterman 2020). Specifically, the CDC reported that among all women with a prior cesarean in the United States, 87.6% of them in 2016 and 86.7% of them in 2018 underwent a repeat cesarean delivery (Osterman 2020).

However, our study aimed to compare patients who had a prior LTCD (N = 1,645,709) versus prior CCD (N = 25,540) and relied on ICD-10 diagnosis codes O34.211 and O34.212, respectively, to distinguish these types of prior cesarean incision. N = 806,939 patients had a prior cesarean delivery, but unfortunately their diagnosis codes lacked specifics about the type of prior cesarean incision. Therefore, they had to be excluded, along with the N = 2,320 patients who had both a prior LTCD and a prior CCD. The rate of repeat cesarean delivery among the patients who were excluded due to unknown type of prior cesarean incision was 79.5%. It appears that documentation of these diagnosis codes for history of prior cesarean incision was more detailed for patients who underwent a repeat cesarean delivery, and hence, the observed rate of repeat cesarean delivery in our prior CCD and prior LTCD sample was higher.

We have revised our study limitations section to acknowledge that our sample was limited to patients with known type of prior cesarean incision and might not reflect the experience of all patients with a prior cesarean delivery. Specifically, we stated the following in lines 229-232:

“… Likewise, some patients had diagnosis codes indicating prior cesarean delivery, but did not specify the type of prior cesarean incision and therefore were excluded from our
analysis. Hence our findings may not be generalizable to all patients with a prior cesarean delivery.”

Reference:


20 - 1.1% vs 0.3% seems like an a rate of uterine rupture consistent with other reported rates.

Thank you.

29 - 36 - well done introduction/epidemiology

Thank you.

58 - Good to exclude both CCD and LTCD. What about Mid or high transverse?

There is no specific ICD-10 diagnosis code to identify patients with a prior mid or high transverse cesarean incision. Therefore, we were not able to identify these patients for assessment in this study. They were excluded along with other patients with an unspecified type of prior cesarean incision.

146 - How was uterine rupture defined? Was this different than uterine window vs asymptomatic uterine dehiscence noted at the time of surgery vs uterine rupture?

We used a rigorous definition of uterine rupture, defined by two ICD-10 diagnosis codes, O71.0 (“Rupture of uterus, spontaneous, before onset of labor”) and O71.1 (“Rupture of uterus during labor”). These codes do not include the spectrum of conditions related to uterine dehiscence, such as uterine window and asymptomatic uterine dehiscence.

Specifically, the Methods section states in lines 75-77:

“Uterine rupture was defined by ICD-10 diagnosis codes O71.0 (“Rupture of uterus, spontaneous, before onset of labor”) and O71.1 (“Rupture of uterus during labor”).”

187-194 - The question of clinical utility is the rate of rupture with labor or the rate of rupture based on gestational age. What was the gestational age at the time of diagnosis?

The primary objective of this current manuscript is to compare uterine rupture rates (and other maternal outcomes) in patients with prior CCD versus prior LTCD while considering patients’ status of labor. In doing so, we adjusted for patients’ gestational age at delivery. However, we recognize that information on rate of uterine rupture based on gestational age is of high clinical utility, and we have therefore pursued subsequent research to more closely examine issues of gestational age. Specifically, in a separate
manuscript, we are studying the relationship between gestational age and labor management decisions within the subset of patients with a prior CCD and the consequences on maternal outcomes (such as uterine rupture). Below is a summary of relevant findings which suggest a higher rate of uterine rupture at earlier gestational ages. Since this will be covered by a separate manuscript, we have chosen to only provide this summary in the response letter for review purpose (without adding to the current manuscript).

<table>
<thead>
<tr>
<th>Gestational Age</th>
<th>Rate of Uterine Rupture</th>
<th>Prior CCD</th>
<th>Prior LTCD</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-31 weeks</td>
<td>60/2175 (2.8%)</td>
<td>145/16,060 (0.9%)</td>
<td></td>
</tr>
<tr>
<td>32-36 weeks</td>
<td>135/7,510 (1.8%)</td>
<td>610/132,900 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>≥37 weeks</td>
<td>75/15,855 (0.5%)</td>
<td>4,155/1,496,749 (0.3%)</td>
<td></td>
</tr>
</tbody>
</table>

195 - 202 - the rate of rupture after labor is a very helpful statistic with this sizable cohort. I would put the raw number of patients prior to the (%) so we can know how large the sample was in line 195-196.

We appreciate this comment and would like to clarify that the requested information is presented in the Results section. Specifically, we stated in lines 158-162:

“… Further examination of uterine rupture by trial of labor status showed that among 23,755 patients with prior CCD who underwent planned cesarean delivery without labor, 80 (0.3%) had a uterine rupture. In contrast, among the subset of 1,785 patients with prior CCD who underwent labor, 190 (10.6%) had a uterine rupture (p<0.001, unadjusted OR 35.25, 95% CI 19.64-63.29).”

The strengths of this paper are:
1. Focused clinical question
2. Large sample size
3. Rigorous statistics to have a robust exclusion criteria and matching to avoid confounding
4. Well-written, clear, thoughtful and clinically useful

Thank you.

Weaknesses/limitations: Overall this is a very interesting and helpful paper. Some things can be done to improve the paper:

1. A flowchart of all the patients into each arm CCD vs LTCD and then again into labor vs no labor then uterine rupture vs no rupture and then again into % who have elevated SMM would be very helpful

In response to this suggestion and the Statistical Editor’s request, we have created a flow chart. Please see new Appendix 2 figure. Because patients who experience SMM and uterine rupture are not mutually exclusive, it is difficult to represent all permutations of these outcomes in a clinically useful way. Moreover, use of the NIS data requires
avoidance of reporting small cells (https://www.hcup-us.ahrq.gov/db/publishing.jsp). Because some of the outcomes have low frequencies (such as uterine rupture), presenting overly complex permutations of the outcomes could pose small cell issues. Therefore, we have chosen to simplify the flow chart by showing the crude and weighted counts for the overall sample, as well as key subsets and their outcomes. This is consistent with the approach suggested by the Statistical Editor in his/her first comment.

2. Do you know the rate of fetal injury after uterine rupture? It would be very helpful clinically to be able to say X% of patients w/ a hx of CCD will have a uterine rupture (with and without labor). For example, perhaps 1/100 patients with prior CCD will have a uterine rupture after labor and 1/100 of those infants will have significant neurologic injury. This should be easily captured through matching maternal and newborn records or searching for neurologic injury for newborns on discharge from the hospital.

We agree that rate of fetal injury after uterine rupture would be useful to clinicians. However, because the NIS data are de-identified, we are unable to link maternal and neonatal records and therefore cannot measure fetal outcomes such as fetal injury.

3. Does not have any comment on prior uterine or uterine surgery - While this is unlikely to be a large number, I would add this as an exclusion criteria.

Although there exists an ICD-10 diagnosis code O34.29 for “maternal care due to uterine scar from other previous surgery,” this code does not indicate whether the endometrial cavity was entered during the previous surgery, which would favor performing a repeat cesarean section. In addition, out of the total sample size of 1,671,249, only N = 2,625 patients had O34.29, representing just 0.16% of the total sample. Therefore, we do not feel it is necessary to include it as an exclusion criterion.

STATISTICS EDITOR COMMENTS:

Lines 122-134, Table 1: Need to state whether the counts were from the NIS or weighted to be representative of the entire US population. Should use a flow diagram to show the crude and weighted counts for the overall data set and key subsets and their outcomes. Since all counts are rounded to either 5 or 0, I suspect that these are all extrapolated by ~ 5x.

The NIS provides a systematic random sample of inpatient stays stratified by hospital characteristics and reflects approximately 20% of all discharges from US community hospitals (https://www.hcup-us.ahrq.gov/tech_assist/sampledesign/508_compliance/index508_2018.jsp). Because 20% of the universe discharges in each stratum were sampled, the discharge weights are near five (https://www.hcup-us.ahrq.gov/db/nation/nis/NIS_Introduction_2019.jsp). All of our analyses were weighted in order to generate nationally representative estimates.

In response to this comment, we added a footnote underneath each table to clarify that “All statistics reported reflect weighted results.” Please see footnotes in revised Tables 1-3.
In addition, we have added a flow diagram detailing both the crude and weighted counts for the overall data set, key subsets, and their outcomes as suggested. Please see the diagram in new Appendix 2.

Table 2: The ORs appear to be based on the crude counts, rather than weighted, extrapolated counts. I concur with this method.

We appreciate this comment and would like to clarify that results in Table 2 reflect weighted results. Since the NIS involved complex sample design, it is necessary to account for the design effects (stratification, clustering, weighting) in our assessment of odds ratios and confidence intervals. We have added a footnote in Table 2 to clarify that results reflect weighted counts of data.

Figs 1 and 2 are placed after Appendices 1 and 2 in my copy. I assume they are in main text, they should be, esp figure 2. Suggest that Fig 2 legend should include that IPTW method was used, even though it is stated in the Figure itself.

We have corrected the order of the figures and appendices. Figures 1 and 2 are now placed before Appendices. In addition, as suggested, we have added a footnote in Figure 2 to clarify that “All models applied propensity score method using inverse probability of treatment weighting.”

EDITOR COMMENTS:

Please include in your Abstract differential rates of uterine rupture by labor or no labor among women with prior CCD.

We have updated the Abstract to include the differential rates of uterine rupture. Specifically, we stated in lines 18–20:

“Among patients with prior CCD, uterine rupture occurred in 10.6% of those who underwent labor versus 0.3% of those who did not labor (p<0.001).”

EDITORIAL OFFICE COMMENTS:

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

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

We have included the requested title page information in the main manuscript file. This study is not a clinical trial nor the result of industry-sponsored research. We have added IRB information to the Methods section. Specifically, we stated in lines 62-64:

“This study was reviewed by the Yale University Institutional Review Board and was determined to be not human subjects research as it only involved secondary analysis of de-identified data.”

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

All authors have been notified and have no disclosures to report.

4. 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.
Classification of race/ethnicity was directly obtained from the NIS database. In the NIS, information on patient sociodemographic characteristics, including race/ethnicity, was abstracted from billing data submitted by hospitals to statewide data organizations across the United States. Patients who were Asian or Pacific Islander, Native American, or had other unspecified or unknown race/ethnicity were combined into one category (labeled as “other or unknown”) due to their relatively small counts. We have revised our Methods section to clarify these points. Specifically, we stated in lines 97-107:

“To inform the potential role of patient sociodemographic characteristics and hospital attributes in affecting the outcomes of patients with prior CCD, we measured maternal race and ethnicity, primary insurance payer, and median household income for the patient’s ZIP code (in quartiles), as well as the delivery hospital’s teaching status, urban-rural location, type of ownership, bed size, and geographic region. Maternal race and ethnicity were categorized as non-Hispanic White, non-Hispanic Black, Hispanic, and other or unknown (including Asian or Pacific Islander, Native American, and other unspecified or unknown race/ethnicity). In the NIS data, patient sociodemographic characteristics and clinical information were abstracted from discharge records, while hospital characteristics were obtained from the American Hospital Association annual survey of hospitals.”

References:


5. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Methods section of the body text, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

We have added IRB information to the Methods section. Specifically, we stated in lines 62-64:
“This study was reviewed by the Yale University Institutional Review Board and was determined to be not human subjects research as it only involved secondary analysis of de-identified data.”

6. 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 (i.e., CONSORT), observational studies (i.e., STROBE), observational studies using ICD-10 data (i.e., RECORD), meta-analyses and systematic reviews of randomized controlled trials (i.e., PRISMA), harms in systematic reviews (i.e., PRISMA for harms), studies of diagnostic accuracy (i.e., STARD), meta-analyses and systematic reviews of observational studies (i.e., MOOSE), economic evaluations of health interventions (i.e., CHEERS), quality improvement in health care studies (i.e., 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.

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We have included a combined STROBE/RECORD checklist in our submission files.

7. Your study uses ICD-10 data, please make sure you do the following:
   a. State which ICD-10-CM/PCS codes or algorithms were used as Supplemental Digital Content.
   b. Use both the diagnosis and procedure codes.
   c. Verify the selected codes apply for all years of the study.
   d. Conduct sensitivity analyses using definitions based on alternative codes.
   e. For studies incorporating both ICD-9 and ICD-10-CM/PCS codes, the Discussion section should acknowledge there may be disruptions in observed rates related to the coding transition and that coding errors could contribute to limitations of the study. The limitations section should include the implications of using data not created or collected to answer a specific research question, including possible unmeasured confounding, misclassification bias, missing data, and changing participant eligibility over time.
   f. The journal does not require that the title include the name of the database, geographic region or dates, or use of database linkage, but this data should be included in the abstract.
   g. Include RECORD items 6.3 and 7.1, which relate to transparency about which codes, validation method, and linkage were used to identify participants and variables collected.

We have included a combined STROBE/RECORD checklist in our submission files.

8. Standard obstetric and gynecology data definitions have been developed through the
reVITALize initiative, which was convened by the American College of Obstetricians and
Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics &
Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data

We have reviewed the reVITALize definitions and confirm that our manuscript content is
consistent with these definitions.

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

The total word count of our revised Original Research manuscript is 4,131 words.

10. Specific rules govern the use of acknowledgments in the journal. Please note the following
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this assistance, whether directly or indirectly.
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Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

We have no acknowledgements to report.

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not contain information that does not appear in the body text. If you submit a revision, please
check the abstract carefully.
In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words; Reviews is 300 words; Case Reports is 125 words; Current Commentary articles is 250 words; Executive Summaries, Consensus Statements, and Guidelines are 250 words; Clinical Practice and Quality is 300 words; Procedures and Instruments is 200 words. Please provide a word count.

This is an Original Research article. Our Abstract contains 300 words.

12. 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.

We confirm that our manuscript only contains standard abbreviations/acronyms and that all abbreviations/acronyms are spelled out at their first use in the abstract and again in the body of the manuscript.

13. 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.

We have revised our manuscript throughout to avoid using the virgule symbol (/), except for places reflecting measurement.

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

We have replaced “provider” with “physician” in line 234 and with “healthcare professionals” in line 239.

15. 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.

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