Author's response to reviews

Title: Determinants of cesarean delivery: a classification tree analysis

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Author's response to reviews: see over
Bologna, June 9, 2014

Dear Editor,

Thank you for the opportunity to re-submit a revised version of our paper. A professional editing service edited the English form of the paper and changes to the text are tracked in Word. We also added an Acknowledgments section, as requested.

We hope that the quality of written English is adequately improved. Please feel free to contact us with any additional questions or comments.

We look forward to your final decision on this paper.

Sincerely,

Elisa Stivanello
We thank the reviewer for his helpful comments.

Major Compulsory Revisions

• Authors should describe more extensively what this study adds to the scientific knowledge already available.

What this study adds to the available scientific knowledge is the relevance of a number of clinical characteristics of the mother and the fetus to the decision to perform a CD. Compared with the existing literature on risk adjustment models, our analytical strategy based on classification tree has the potential to identify subgroups at risk of CD characterized by combinations of maternal characteristics, obstetric and organizational variables. This paragraph has now been added to the Discussion (third paragraph).

Minor Essential Revisions

• Page 2, line 45. The conclusions in the abstract seem very vague. Probably, it would be useful to discuss briefly the concepts of "appropriateness of CD" and "audit activities."

We have rephrased the last sentence of the abstract mentioning the need of audit activities.

• Page 10, line 227. It is not clear what the authors mean: "primiparous women" or "women with no previous cesarean sections".

By "primiparous women" we mean "women at their first delivery". It is important that the first delivery is not a CD because usually after a first CD the risk of repeat CD is high.

• Among the "organizational variables", activity volumes (number of births per year) and hospital type were considered in the analysis. These variables refer to a higher hierarchical level than the primary unit of interest (the "birth", which can be vaginal or surgical). This could alter the statistical properties of the classification trees (in the statistical literature this question is still open and there are no unique solutions to handle multi-level structures in the context of classification trees). Therefore, I propose to make a further sensitivity analysis excluding these "contextual" variables and then compare the results.
We thank the reviewer for raising this point. We acknowledged his suggestion and carried out this further sensitivity analysis, whose results are illustrated in the figure below. Results are the same as those of the primary analysis, and methods and results have now been extended (P. 8, Ln 15-17; P. 10, Ln 17-19).

We thank the reviewer for noticing this inaccuracy, and replaced “CeAP” with “CedAP”.

Minor revisions

List of abbreviations, page 11, line 265: replace “CeAP” with “CedAP”.

We thank the reviewer for noticing this inaccuracy, and replaced “CeAP” with “CedAP”.
We thank the reviewer for the helpful comments.

Major Compulsory Revisions

Given that several of your decision points relate to factors already used in the TGCS (previous scar, malpresentation, and parity), can you provide more information on how your classification tree analysis is an improvement over assessing indications for CD within specific TGCS groups?

While the 10-group classification was designed to compare CD rates over time in one unit and among different units, or different countries, our analytical strategy was aimed at identifying clinical determinants of CD that might be relevant for audit purposes because they characterize specific CD risk subgroups not captured by the TGCS variables alone. These considerations have now been added to the Discussion (third paragraph).

In the model excluding fetal distress/dystocia, fetal weight at delivery was included as a determinant of CD; however, fetal weight is not accurately known until after delivery. Can you address the practical implications of using a variable that cannot be collected prospectively in your decision tree?

We understand that fetal weight is not accurately known until delivery. Still, we used this variable to reflect the ex-post decision to perform the cesarean. This variable, classified into broad categories, proved to have a higher discriminating power than gestational age in the classification tree because it identifies both newborns with low gestational age (X TGCS class, in which the mean probability of CD is 50% across studies; Colak et al., 2012) and newborns with fetal growth retardation, regardless of gestational age, for which the CD might be indicated.

It would be helpful to readers if you can provide any information on the reliability and validity with which diagnoses are coded in your dataset, or any changes in documentation and coding practices and standards during the study period, especially re: fetal distress and dystocia. You provide references in the discussion that in other contexts these indications may be present on medical charts as justifications after the fact, or that the necessity for cesarean for selective diagnoses offers questionable benefit (p 10 paragraph 2) but the extent to which this may be relevant in your context is not discussed. This may also have implications re: whether diagnostic codes of fetal distress alone comprise the optimal definition to be used in your
classification tree (rather than a combination of diagnostic codes and other maternal or newborn/fetal information that may be available from your administrative data).

In Emilia-Romagna Region quality improvement is promoted through training of coders and a regular review of the hospital discharge records database at the Regional Health and Social Care Agency, with feedback to the hospital coders about logical inconsistencies and the presence of systematic errors. The use of ICD-9-CM for coding diagnoses and procedures is established since 2002, thereby facilitating the consistency of coding across operators. This consideration has now been added to the Discussion (P. 13, Ln 13-18).

Unfortunately information on the validity and reliability of fetal distress diagnosis is not available and we generalized to our setting the observation that the use of this diagnosis might be a post-hoc justification of the CD. However, we can confirm that during the index period no change has been introduced in coding procedures for fetal distress and uterine dystocia.

Discrepancy Revisions

Page 3, lines 70-71, change text to “Italy has one of the highest CD rates in the world.”

We changed the sentence, as suggested (P.4, Ln 20).

Page 10 line 244: You note that ICD codes may be more likely to be omitted in the vaginal delivery group, but do not discuss the inverse possibility: diagnoses may be more likely to be documented and subsequently ICD coded in the group with CD. Are there implications associated with this for your study?

We thank the reviewer for the opportunity to clarify this point, and we expanded the discussion to include potential implications. Because the study population includes women in childbearing age, that are generally healthy, comorbidities are uncommon (Stivanello et al., 2013). However, we agree that a more accurate documentation of other clinical risk factors might lead to an information bias. We have acknowledged this point as a limitation in the Discussion (P.13, Ln 7-10).

Minor Essential Revisions

Line 239, replace ] with )

We thank the reviewer for noticing this inaccuracy. The text has been changed, as suggested.
#3 - MARIA REGINA TORLONI

We thank the reviewer for the helpful comments.

Introduction

1. I suggest that you modify this sentence: "... which combinations of 73 demographic, clinical and organizational variables best distinguish cesarean deliveries..." with "... which combinations of 73 demographic, clinical and organizational variables best predict which women are at higher risk for cesarean deliveries..." (Minor Essential Revision)

We acknowledged the reviewer's suggestion and rearranged the sentence, as requested (P. 4, Ln 21-22).

Methods

2. Why didn’t the authors include epidural rates and instrumental delivery rates in their model? These variables could potentially increase CD rates (see Joyce 2002), since women may prefer a CD in setting where epidural analgesia is not available 24h/day, 7 days/week. Similarly, the rates of CD would probably be higher in settings where operative vaginal deliveries (forceps, vacuum) are rare, because of staff lack of training or hospital policy. If these variables were not available in the form used for this study, then point to this fact as a possible limitation of this study. (Major Compulsory Revision)

The reviewer is right in mentioning these points. We did not include these variables for several reasons. Information about epidural analgesia was not available for the entire period of observation because it was collected starting from 2007. Information on operative vaginal deliveries was available but we did not include it in the model because these procedures were rarely used and were uncorrelated or weakly correlated with the CD rate. In 2012 the forceps was used in less than 0.1% deliveries in Emilia Romagna Hospitals (ranging from 0 to 0.4%), vacuum was used in 4.2% deliveries (ranging from 1.6 to 7.9%) with a low negative correlation (-0.26) between CD rate and vacuum use. This information has been added to the Methods section (P. 7, Ln 6-9).
3. Line 87-89: clarify the meaning of all the codes mentioned. This could be added as a box or an online annex (Discretionary Revision)

We acknowledged the reviewer’s suggestion and added a supplementary PDF file (Additional file 1) with a detailed list of all codes included in the analysis.

4. Line 93: review this statement, there is something missing: “Mothers discharged from hospitals without an operating room (Code? Procedure? Intervention?) and...” annex (Minor Essential Revision)

We have better specified our exclusion criteria: 1) all mothers discharged from a hospital without an operating theater, and 2) mothers with one of the following discharge diagnoses: 656.4 (intrauterine death), V27.1 (single stillborn), V27.4 (twins, both stillborn), and V27.7 (multiple birth, all stillborn). See P.5, Ln 21-22.

5. Line 109: exclude the last 3 words “premature rupture of membranes of the amnions,” (Minor Essential Revision)

We deleted the last three words, as suggested (P.6, Ln 17).

6. Line 109: Please clarify what “other problems of the amnions” refers to, besides polyhydramnios, oligohydramnios and premature rupture of the membranes. (Minor Essential Revision)

The category “Other problems of the amnions” includes 658.4, 658.8, 658.9 ICD-9 codes that encompass infections of the amniotic cavity. We have changed the text (P.6, Ln 18) and Table 1 to clarify this point.

7. Line 112: Correct limits of birthweight categories to match those presented on Table 1. (Minor Essential Revision)

We used these birth categories for the analyses: \( \leq 1500, 1501-2499, 2500-3999, \) and \( \geq 4000 \) g. We thank the reviewer for noticing this inaccuracy, and corrected the limits both in the text (P.6, Ln 21) and in Table 1.

8. Lines 115-116: Clarify to which group a delivery at exactly 7 AM or 7 PM would belong. The current sentence states: “time of delivery (between 7 a.m. and 7 p.m. or between 7 p.m. and 7 a.m.)”. (Minor Essential Revision)

7:00 a.m. and 7:00 p.m. belong to the category of nighttime deliveries. The sentence has been corrected, as suggested (P.6, Ln 25).
9. Line 118-119: Clarify to which group an infant weighing exactly 2500 g would belong. The current sentence states: "... mean annual number of deliveries categorized as: <500, 501–799, 800–999, 1000–2499, >2500 deliveries per year... “ (Minor Essential Revision)

We thank the reviewer for noticing this inaccuracy; 2500 deliveries per year belongs to the last class of volumes. Text (P 7, Ln 3) and Table 1 have been changed accordingly.

Results

Suggested modifications to improve Table 1 (all Minor Essential Revision)

10. - Add a first line with the overall rate of CS for the whole population

The last row, which reports the overall rate of CS for the whole population, has been relocated at the beginning of Table 1.

11. - Add “country” after High income and Low income

We acknowledged the reviewer’s suggestion and added the term “country”.

12. - Create a new heading (for example “Obstetrical conditions” under which you should group the list of conditions currently under “Comorbidities”, starting with Previous stillbirth/abortion. I suggest that you order the list of conditions under Comorbidities and Obstetrical conditions in ascending order of percentage of CD (last column).

We added a new heading and listed comorbidities and obstetrical conditions in ascending order of % of CD, as suggested.

13. - Correct the text of Methods so that the categories for Birth weight match those presented on this table.

We thank the reviewer for noticing this inaccuracy. Birth weight categories presented in Table 1 now match with those reported in the text (see Point 7).

14. - Present parity as: nullipara and multipara (1 or more) with the corresponding CD percentage for each.

Percentages of CD for nullipara and multipara are now provided separately, as suggested.

15. - Add a line for “Delivery on working days” with % of CD, to compare with current information on non-working days.

Percentages of CD in working and non-working days are now provided separately, as suggested.
16. Add a line for day time deliveries with % of CD, to compare with current information on night-time deliveries.

Percentages of daytime and nighttime CD are now provided separately, as suggested.

17. Figure 1: Emphasize (using bold characters or underlining) the numbers that represent the likelihood of CD in each of the 8 boxes. (e.g. Node 1: 93%, Node 2: 22.4%, etc.) (Minor Essential Revision)

We thank the reviewer for her suggestion. Unfortunately, SPSS allows changing font and size for all text in the tree, but not for individual lines or branches. However, we have redone the figures so that the 'CD' category and its likelihood can be easily identified.

18. Provide a clearer explanation why the 4 variables included in Fig 1 were the ones chosen for this tree (and not the others, such as for instance “Dystocia”). This explanation should be comprehensible for the average reader, without a statistical background. (Minor Essential Revision)

We thank the reviewer for raising this point. As stated in the Statistical analysis section, in CRT analysis “the best discriminating predictor is selected first and then subsequent predictors are entered into the procedure if they contribute significantly to sub-typing cases that are homogeneous groups in terms of the value of the dependent variable”, and “the tree is grown until stopping criteria are met, and then it is trimmed automatically to the smallest sub-tree based on a pre-specified maximum difference in risk”. In other words, the final tree contains only those variables which contribute significantly to sub-typing homogeneous groups of women in terms of CD rates; that is, it includes only relevant predictors of CD. No arbitrary choice was therefore made. This has now been clarified in notes to Figures 1 and 2.

19. On line 183 (referring to Fig 2, sensitivity analysis), the authors state that they excluded fetal distress and dystocia from the previous model. However, dystocia was not part of the previous model. Please clarify. (Minor Essential Revision)

We acknowledge that this point needs clarification. Dystocia was included in the primary analysis, but it was not selected as a predictor of CD by the CRT algorithm. This is now better explained in notes to Figures 1 and 2 (see Point 18).

Discussion

20. Line 198: I suggest that you modify “... best distinguish cesarean deliveries...” to “... best predict which women are at higher risk for cesarean deliveries...” (Minor essential revision).
We acknowledged the reviewer's suggestion and rephrased the sentence as follows: "... best predict which women have a higher risk of cesarean delivery" (P. 10, last line).

21. Change "pluriparity" for "multiparity" throughout the manuscript. (Discretionary Revision)

We acknowledged the reviewer's suggestion and changed "pluriparity" with "multiparity" throughout the manuscript.

Conclusion

22. The 2nd sentence is too long. Consider breaking it down into 2 smaller sentences, for the sake of clarity. (Discretionary Revision)

We have broken down the sentence into two parts as suggested.

References to include/modify


We updated reference #3, as suggested.


We thank the reviewer for this suggestion and added this reference as reference #29.