Author’s response to reviews

Title: The trend of caesarean birth rate changes in China after ‘universal two-child policy’ era: A population-based study in 2013-2018

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Author’s response to reviews:

Dear editor and reviewers,

First of all, thank you so much for all your comments and suggestions on the current study. We appreciate that we could have this opportunity to revise the manuscript. In the revised version, you could find we have made some major changes according to the reviewers’ comments. Firstly, the project was initially set to promote reproductive health of rural resident couples and gradually expanded to the whole population since 2013. In the 2011 and 2012 were two trial years for the study. Thus, the sample size was much smaller than that in 2013-2018. In the revised analysis, we
now excluded data from year 2011 and 2012 to maintain the similar sample size. Secondly, in order to explain how the policy affected the rate of caesarean delivery as reviewers suggested, we analyzed data using interrupted time series (ITS) analysis with segmented linear regression to evaluate the change of caesarean section rates over time. We revised the results and expand discussion accordingly. After the major changes, we could answer most of the questions from reviewers and make our conclusions are more reliable. Please find the detailed point-by-point responses below. Thanks again for all your brilliant ideas and recommendations.

Reviewer reports:

Handong Li (Reviewer 1): This paper analyzes the trend of caesarean delivery rate in 2011-2018, and represents some indicators, such as crude rate, standardized rate, and marginal effects of year, by participants' residential registering type and regions of provinces, respectively. And the author discusses the possible reasons for the change of caesarean delivery rate. The population-based data used in the analysis are from NFPCP related questionnaires, and two rounds of follow-up interviews.

Comments
1) Based on the empirical data, the author gives a brief descriptive analysis, such as the annual changes of caesarean delivery rate. Although the author lists the relevant variables collected in the data, which are represented in part of 'Covariates', but the paper lacks a specific discussion of the correlations or quantitative analysis between covariates and caesarean delivery rate. Therefore, it maybe make the conclusion more complete with a further analysis of the correlations mentioned above.
Response: Thanks for your point. You are right, we only gave a brief descriptive list of the relevant covariates in the previous submission. In the revision, we did a quantitative analysis between covariates and caesarean delivery rate. We added the data to the Supplementary Table 1. This analysis definitely make the conclusion more complete.

2) Some of the conclusions in this paper is vague, such as the impact of 'universal two-child policy' on the change of caesarean delivery rate. The author does not explain how the policy affected the rate of caesarean delivery. Has the policy influenced the proportion of women with uterine scar, or has it increased the number of women who have a willingness to have a second child? We cannot find a clear answer in this paper. Add details to the point will make the conclusion more reliable.
Response: This is a great point. In order to explain how the policy affected the rate of caesarean delivery as reviewers suggested, we analyzed data using interrupted time series (ITS) analysis with segmented linear regression to evaluate the change of caesarean section rates over time. ITS can be used to evaluate the longitudinal effects of the intervention (e.g. universal two-child policy). It allows us to assess, in statistical terms, how much an intervention changes the outcome of interest, both immediately and over time. The ITS data has been added to Figure 2 and Supplementary Table 3. For standardized rate, ITS showed the caesarean delivery rate decreased by 0.1% (95% CI: 0.1-0.1) per month before the release of universal two-child policy, 4.2% (95% CI: 3.4%-5.0%) absolute drop during the policy release month, and increased by 0.2% (95% CI: 0.1%-0.2%) per month after the policy implementation.
3) In the part of 'Statistical analysis', the author calculates the crude rate using data from NFPCP study which mainly targeted participants from rural areas in which the caesarean delivery rate was relatively lower. While the author uses age structure from 1% national population sample survey in 2015 to standardize caesarean delivery rate. Are there characteristics of age-specific crude rate from NFPCP consistent with the national age-specific rate? Is there any adjustment to this problem in the process of standardization?

Response: Thanks for your comment. After reviewing available literatures, we found only one published paper outlining the age-specific rate from 438 hospitals in China between 2012-2016 [Liang J, Mu Y, Li X, Tang W, Wang Y, Liu Z, et al. Relaxation of the one child policy and trends in caesarean section rates and birth outcomes in China between 2012 and 2016: observational study of nearly seven million health facility births. BMJ. 2018;360:k817.]. We compared data and found both the overall rate and age-specific rate of caesarean delivery in NFPCP are lower than the national rates. In NFPCP, most participants were rural residents, which had lower caesarean delivery rate compared to urban residents. Besides, the potential intervention effects of NFPCP could also attribute to this. At preconception health examination, NFPCP participants were advised to take control of risk factors related to caesarean delivery rate before conception, e.g. losing weight for overweight or obese participants, or recommendation of avoiding unnecessary caesarean delivery. Except for external comparability, we used standardized rate to make the yearly rate to be comparable internally in the current study.

4) There are some typing errors in the manuscript. For eg. Page 22, line 6, wrong reference number: …from 9.8% to 17.7% (9)…

Response: Thank you so much for the comment. We have corrected the wrong reference number.

Yanhong Gong (Reviewer 2): Thank you for the opportunity to review this paper. The document aimed to study the caesarean delivery rate affected by the universal two-child policy using a large amount of data from NFPCP. However, it provided inadequate analyses and some descriptions of this paper are imprecise and inappropriate. It should be carefully polished furthermore.

Here are some queries which I will like the authors to address.

Abstract
1.Line 58, there is a lack of statistical analysis in the method section.
Response: Thanks for the comment. We have added the statistical analysis in the method section in the abstract [page 3-4, line 59-61].

Background
1.Line 81, please provide the references for the risks of cesarean delivery.
Response: Thanks for the comment. We have provided references for the risks of cesarean delivery [page 6, line 87].

2.Line 107, it is better to briefly describe what the "universal two-child policy" is.
Response: Thanks for the comment. The brief description of “universal two-child policy” has been added: “The relaxation of the one child policy in November 2013 allowing couples in which at least only-child of either parent to have two children and the introduction of the universal two-
child policy in October 2015 allows each married couple to have two children.” [page 7, line 112-114].

3.Line 108, "affect the caesarean rate by influencing women's expectations and choices", it is necessary to specify what the "women's expectations and choices" are and how influence.
Response: That is a very important point we need to further address. We have explained the "women's expectations and choices". For primiparas, vaginal birth was the primary choice of delivery method. Caesarean delivery on maternal request was not as widely accepted, in contrast to previous years. Women were aware of and took into consideration the consequences of caesarean delivery for future pregnancies. For multiparas with previous caesarean delivery, repeat caesarean delivery remains the norm. [Reference: Wang E, Hesketh T. Large reductions in cesarean delivery rates in China: a qualitative study on delivery decision-making in the era of the two-child policy. BMC pregnancy and childbirth. 2017;17(1):405.] [page 7, line 117-121].

Methods
1.Line 147-151, this paragraph should be demonstrated in the Results Section.
Response: Thanks for the point. We have moved this paragraph to the “Results” section.

2.Line 148, why choose the women who were aged 20-49 years old at delivery as the study participants?
Response: Thanks for your question. The childbearing age for women is usually between 15-49 years old and the legal marriage age for women starts from 20 years old in China. Therefore, we chose the women who were aged 20-49 years old as our study participants.

3.Line 156 and 190-191, the statements of covariates and "reference levels of covariates" are confusing. In my opinion, for example, nationality should be one of the covariates and Han nationality should be reference level of this covariate.
Response: Thanks for your question. We have changed the reference levels as reference level for covariates: age was ‘25-29 years’, BMI was ‘normal weight’, nationality was ‘Han nationality’, education was ‘no higher education’, household register type was ‘rural’, adverse pregnancy outcome history was ‘without adverse pregnancy outcomes’, parity was ‘primipara’, full-term births was ‘yes’, and number of fetus was ‘singleton’. [page 11, line 201-205].

4.Line 177, why used age structure from 1% national population sample survey in 2015 to standardize caesarean delivery rate?
Response: Standardized rate used in current study is to make the results comparable with external studies and internal results among different study years. Additionally, as 2015 is the nearest year of national population census or sample survey, and to make the standardized rate more comparable with the recently studies or reports, we used 1% national population sample survey in 2015 to standardize rate.

Results
1.Line 214-215, "low-risk birth which is defined as......" there appears to be repetitions of descriptions for the "low-risk birth".
Response: Thanks for your point. We have removed the repetition of descriptions for the “low-risk birth”.

2. The values in Table 1 and Table 2 were shown irregularly, some of the figures were presented with one decimal place, while some were presented with two. In addition, there was no footnote to explain the meaning of abbreviations as well as numbers inside and outside brackets.
Response: We appreciate your point. We now presented data with one decimal place and added footnote to explain the meaning of abbreviations as well as numbers inside and outside brackets.

3. Please provide the overall cesarean rate across all included regions.
Response: Thank you. That is a really important point. We have added the overall cesarean rate in the Figure 2 and Supplementary Table 2.

4. I suggest authors to try to analyze the cesarean rate by nulliparous and multiparous women, respectively, which may provide more information. Because these two groups may have significant difference in delivery modes.
Response: Thanks for the comments. We now analyzed the cesarean delivery rate by primiparous and multiparous, respectively. We also believed this analysis could provide more information. For primiparas, vaginal birth was the primary choice of delivery method and for multiparas with previous cesarean delivery, repeat cesarean delivery remains the norm.

Discussion
1. Line 271-272, the study did not report an overall cesarean delivery rate at all, and there was no any reference for the previous publications. However, the authors have devoted a large chunk of "Discussion Section" (line271-282, and line300-308) to clarify the issue.
Response: Thanks for your comments. We have added the overall cesarean rate in the Figure 2. In the previous discussion, we did spend a large chunk of “discussion” to compare our “cesarean delivery rate” with the other studies. In the revision version, we removed some of these contents and focused on the cesarean section rate changes before and after the “universal two-child policy”.

2. Line 284, I think this statement is improper, for there is no evidence for this statement based on the findings presented.
Response: Thanks for your comments. We have deleted the statement. [page 21, line 322-323].

3. These sentences are hard to understand. "we could not … universal two-child policy. Nevertheless……and low-risk women." (line 369-372), please clarify.
Response: Thanks for your comments. We have deleted the statement. [page 25, line 405-410].

Conclusions
1. Line383-384, "China is seemed to … in cesarean deliveries", there is no evidence for this statement based on the findings presented in the study, it should be removed.
Response: Thanks for your comments. We have deleted the statement.

Xiu Qiu (Reviewer 3): In this manuscript, the authors used nationwide data to evaluate the caesarean section rate from 2011 to 2018 in China and assess the change of the rates after the
implementation of the universal two-child policy. Considering the major issues existing in this study, I am hesitating to suggest this manuscript to be published in BMC Medicine.

My major comments are as follow:

1. This study fails to answer whether the universal two-child policy did contribute to the change of the caesarean section rate due to its inappropriate study design and methodology.
Response: Thanks for your comments. As you suggested, in order to explain how the policy affected the rate of caesarean delivery, we analyzed data using interrupted time series (ITS) analysis with segmented linear regression to evaluate the change of caesarean section rates over time and how much an intervention changes the outcome of interest. The ITS data has been added to Figure 2 and Supplementary Table 3.

2. Representativeness of the study sample is unknown. In 2011 and 2012, the sample size (194,059 and 567,574, respectively) is far smaller than that in 2013-2018. It is necessary to present the proportion of births in this sample to the total births in the country, as well as the region-specific proportions.
Response: The project was initially set to promote reproductive health of rural resident couples and gradually expanded since 2013. In the 2011 and 2012 were two trial years for the study. Thus, the sample size was much smaller than that in 2013-2018. In the revised analysis, we now excluded data from year 2011 and 2012 to maintain the similar sample size. According to the data from National Bureau of Statistics of China (http://data.stats.gov.cn/easyquery.htm?cn=C01&zb=A03060D&sj=2019), we could get the total births in China and further calculate the proportion of births in this sample to the total births in the country. The proportion was around 8.2-10.7% between 2013 and 2018 (Table). Unfortunately, the data of region-specific births are not available, thus we could not provide the region-specific proportions currently.

Table. The proportion of births in this sample to the total births in the country.

<table>
<thead>
<tr>
<th>Year</th>
<th>Total births in China</th>
<th>Sample size in the study</th>
<th>The proportion of the study (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>164374981691993316591663179060951727869415265457</td>
<td>136038418137531552952170693917096371254380</td>
<td>8.310.79.49.59.98.2</td>
</tr>
</tbody>
</table>

3. Findings of this study do not provide new implications for controlling caesarean section rates in the context of the universal two-child policy.
Response: Liang et al. reported the caesarean delivery rate between 2012 and 2016 and concluded that China is seemed to be the only country that has succeeded in reversing the rising trends in caesarean deliveries [Liang J, Mu Y, Li X, Tang W, Wang Y, Liu Z, et al. Relaxation of the one child policy and trends in caesarean section rates and birth outcomes in China between 2012 and 2016: observational study of nearly seven million health facility births. BMJ. 2018;360:k817]. Although universal two-child policy has been implemented in China for several years till now, there is lack of data regarding the contribution of the policy on the caesarean delivery rate. Our study provided more lines of evidence regarding the caesarean delivery rate before and after “universal two-child policy” and identified several high risk factors (advanced maternal age, higher education level, overweight and obese women, complicated with adverse pregnancy
outcomes in previous deliveries) for increasing caesarean delivery rate. In the current study, there is a noticeable increase of caesarean delivery rate which is identified in 2017 and 2018, only 2-3 years after the “universal two-child policy”, although a significant but temporary decrease of caesarean delivery rate was appeared in 2016. It reminds us that the caesarean delivery control is still a long-process and all the strategies need to be continually reinforced not only in multiparas, but also in primiparas, such as promoting trial of labor after caesarean (TOLAC), performing external cephalic version for breech presentation, providing nutritional management during pregnancy to realize optimal maternal weight gain and avoid macrosomia.

Other comments/suggestions include:

1. Please include the aims of this study in the Background section of Abstract.
Response: Thanks for your comment. We have added the aim of this study to the abstract. [page 3, line 48-49].

2. Please add a brief description of statistical analyses in the Methods section of Abstract.
Response: Thanks for your comment. We have added the statistical analyses in the methods section of Abstract. [page 3-4, line 59-61].

3. Please clearly specify in Abstract and the Methods section that the present study is a retrospective one.
Response: Thanks for your comment. We have clarified the present study is a retrospective one in the methods section of Abstract. [page 3, line 52; page 8, line 132].

4. Line 88-90: "In China, the caesarean delivery rate increased dramatically during the past three decades (2-5)." References 2-5 were published between 1990 and 2001, which could not reflect the change "during the past three decades". Please also refer to more recent reports.
Response: Thanks for your comments. We have added two more recent references here. The World Health Organization (WHO) reported that 46.2% of births were delivered by cesarean in the years 2007 AND 2008, based on an analysis of 14541 deliveries in 21 hospitals in 3 provinces. [Lumbiganon P, Laopaiboon M, Gulmezoglu AM, Souza JP, Taneepanichskul S, Ruyan P, et al. Method of delivery and pregnancy outcomes in Asia: the WHO global survey on maternal and perinatal health 2007-08. Lancet. 2010;375(9713):490-9.]

5. Line 125-127: "The project was initially set to promote reproductive health of rural habituated couples and gradually expanded to the whole population since 2013." As the proportion of urban participants in this study ranged from 3% to 9% even after the expansion, far lower than the actual proportion of 53-59% in China, the expression "expanded to the whole population" may not be appropriate here. Please provide more details regarding how this project was expanded. Also, in the Results section, there are still data from urban participants in 2011 and 2012. The authors should explain where these data came from.
Response: Thanks for your comments. We need to clarify the project. The national project was initially set to promote reproductive health of rural resident couples and then gradually expanded to also cover urban resident couples since 2013. Even after the expansion, the national project still mainly focused on the rural areas. Thus, the proportion of the urban participants in this study was lower than the actual proportion of urban residents in China. In the 2011 and 2012 were two trial years for the study. Thus, the sample size was much smaller than that in 2013-2018. In the revised analysis, we now excluded data from year 2011 and 2012 to maintain the similar sample size. There are still some data from urban participants in 2011 and 2012. The national program mainly supported the trial in rural areas in 2011 and 2012, whereas some local programs joined the national program and also reported data collected from urban participants.

6. For the statistical method, the authors could consider using interrupted time series (ITS) analysis with segmented linear regression to evaluate the change of caesarean section rates over time. ITS can be used to evaluate the longitudinal effects of the intervention (e.g. policy). It allows us to assess, in statistical terms, how much an intervention changes the outcome of interest, both immediately and over time, and whether factors other than the intervention can explain the change. Response: This is a great point. In order to explain how the policy affected the rate of caesarean delivery as reviewers suggested, we analyzed data using interrupted time series (ITS) analysis. The ITS data has been added to Figure 2 and Supplementary Table 3. The analyses provided more information regarding the effects of the universal two-child policy.

7. Please specify in the Methods section the p-value threshold for statistical significance. Response: Thanks a lot for your comment. We have added the p-value threshold for statistical significance. [page 11, line 227].

8. When presenting results, it is not necessary to keep two decimal places for percentages. One decimal place would be enough. Response: We appreciate your point. We now presented data with one decimal place.

9. Please specify what number (caesarean section cases or total participants) "no." represents in Table 2. Response: We appreciate your point. We now have clarified it in the footnote of the table.

10. Fig 2 simply replicates the results in Table 2. I suggest combining Table 2 and Fig 2 to incorporate both tabular and graphic data. Response: Thanks for your suggestion. We have put Table 2 in supplementary materials in this revised version.

11. Table 2, Fig 2, and Fig 3 only present the data of total births and low-risk births. It would be better if the authors could additionally show the data of other births (i.e. those other than low-risk births). Response: Thanks for your great point. It is essential to present data both in “low-risk” and “non low-risk”. Similarly, we now analyzed the caesarean delivery rate by primiparous and multiparous, respectively. We also believed this analysis could provide more information.
12. Please include in the Discussion section what new findings/evidence this study adds to the literature, in the context of other similar studies about caesarean section rates in China.

Response: Liang et al. reported the caesarean delivery rate between 2012 and 2016 and concluded China is seemed to be the only country that has succeeded in reversing the rising trends in caesarean deliveries [Liang J, Mu Y, Li X, Tang W, Wang Y, Liu Z, et al. Relaxation of the one child policy and trends in caesarean section rates and birth outcomes in China between 2012 and 2016: observational study of nearly seven million health facility births. BMJ. 2018;360:k817]. Our study provided more lines of evidence regarding the caesarean delivery rate before and after “universal two-child policy” and identified several high risk factors (advanced maternal age, higher education level, overweight and obese women, complicated with adverse pregnancy outcomes in previous deliveries) for increasing caesarean delivery rate. In the current study, there is a noticeable increase of caesarean delivery rate which is identified in 2017 and 2018, only 2-3 years after the “universal two-child policy”, although a significant but temporary decrease of caesarean delivery rate was appeared in 2016. It reminds us that the caesarean delivery control is still a long-process and all the strategies need to be continually reinforced not only in multiparas, but also in primiparas, such as promoting trial of labor after caesarean (TOLAC), performing external cephalic version for breech presentation, providing nutritional management during pregnancy to realize optimal maternal weight gain and avoid macrosomia.

13. The present study shows that the caesarean section rate increased even in low-risk women. It would be better if the authors could expand the Discussion and provide more reasons that could possibly explain this finding.

Response: Thanks for the point. In the revision, we now analyzed the caesarean delivery rate by primiparous and multiparous. At the early beginning of the release of universal two-child policy, the decreased rate could be explained by the influence of the policy on choices of primiparas. For primiparas, vaginal birth was the primary choice of delivery method. Elective caesarean delivery was not as widely accepted, in contrast to previous years. Women were aware of and took into consideration the consequences of caesarean delivery for future pregnancies. [Reference: Wang E, Hesketh T. Large reductions in cesarean delivery rates in China: a qualitative study on delivery decision-making in the era of the two-child policy. BMC pregnancy and childbirth. 2017;17(1):405.]

As the time goes on, the caesarean delivery rate also increased in primiparas. We did a quantitative analysis between covariates and caesarean delivery rate. We added the data to the Supplementary Table 1. We found advanced maternal age, higher education level, overweight and obese women, complicated with adverse pregnancy outcomes in previous deliveries et al. were risk factors to increase caesarean delivery. And Table 1 showed the basic characteristics of the study participants. We could see the proportions of participants with above risk factors were increased from 2013-2018. This might partially explain the Caesarean delivery rate also increased in the primiparas.

14. Line 342-343: "Feeling fatigue or physical strength overdraft probably make obstetricians are prone to use caesarean deliveries." This argument seems too arbitrary. Please provide any evidence to support it.

Response: Thanks a lot for your comment. We have deleted this statement.

15. Strengths of the present study should be added in the Discussion section.
Response: Thanks a lot for your comment. We have added the strengths of the present study in the discussion section. [page 24, line 387-400].

16. Line 383-384: "China is seemed to be the only country that has succeeded in reversing the rising trends in caesarean deliveries." This is not the conclusion drawn from the present study. Please remove it from the Conclusion section.
Response: Thanks a lot for your comment. We have deleted this statement.

17. In academic writing, phrases like "don't" and "didn't" (Line 70, 334, 357, 384) should be avoided and changed into "do not" and "did not".
Response: Thanks a lot for your comment. We have changed "don't" and "didn't" to "do not" and "did not".