Archives of Pediatric Infectious Diseases
Volume 13 · Issue 4 · e156824

OPEN PEER REVIEW

Adverse Neonatal Outcomes Associated with COVID-19: A Case-Control Study in Pregnant Women

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SUBMITTED	REVISED	ACCEPTED	DOI
5 Oct 2024	25 Mar 2025	27 Apr 2025	10.5812/apid-156824

About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

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1 Original submission

2 comments · 14 Nov 2024 – 20 Nov 2024

Referee 1 Reviewer

MINOR REVISION 14 Nov 2024

Dear Author
Thank you for your submission.
This is a well-written article, but English editing is still needed.
There are some notes:
Introduction:
1- Please focus on your objective, give one important result, especially from Iran, and describe the overall pregnancy conditions in your province.
2- There is no need to talk about MERS.
Material and Method:
1- What are the criteria for documented COVID19 disease?
2- How did you calculate the number of cases in your study?
Result:
1- Table 1 may include information about other possible parameters affecting neonatal outcomes.
Discussion:
1- Please shorten the text to focus on your findings and those of other authors, addressing the results one by one. Accordingly, this part may become more oriented toward your results.
Acknowledgement:
Please give the names of your coworkers if you wish to acknowledge them.
Best Regards

Referee 2 Reviewer

MAJOR REVISION 20 Nov 2024

major review

2

Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Editor,

I would like to express my gratitude to you and the reviewers for your thoughtful and constructive comments on our manuscript. Your feedback has been invaluable in improving the quality of our work.

We have carefully addressed all the points raised by the reviewers, and the manuscript has been revised accordingly. The revised parts were highlighted in yellow. Below, I provide a detailed response to each comment.

We hope that the revised manuscript meets your expectations, and we are happy to provide any further clarification or revisions if necessary. Once again, thank you for your time and consideration.

Sincerely,

M. R.

Reviewers' Comments:

Reviewer 1:
Dear Author
Thank you for submission .
This is a well written article but English edition still is needed There are some notes

Answer: Done. The manuscript was edited totally.

Introduction:

1- please focus on your objective, give one important result specially from iran and the overall pregnancy condition in your province

Answer: Done. The important result was added.

2-There is no need to talk about MERS

Answer: Done. The parts talking about MERS was deleted.

Material and Method:
1- what is the criteria for documented COVID19 disease

Answer: The case group included medical records of pregnant women admitted to the maternity ward with COVID-19 infection during pregnancy, confirmed by a positive RT-PCR test, provided the records were complete.

2- How did you calculated the number of cases in your study

Answer: Our study included 180 pregnant women divided into two groups: 1-Case group (n=90): This included pregnant women with a documented history of COVID-19 infection during pregnancy, confirmed through positive RT-PCR test results, and with complete medical records. 2- Control group (n=90): These were matched individuals with no history of COVID-19 infection during pregnancy, matched based on age, type of delivery, and parity. This selection was based on the admissions of pregnant women to the maternity ward at Ali-Ibn-Abi-Taleb Hospital over the study period (September 2020 to September 2021) and adhered to the defined inclusion and exclusion criteria mentioned in the methodology.

Result:
1- Table 1 may have the information about possible other parameters affecting neonate outcome.

Answer: We included all available and documented data in our study. The parameters presented in Table 1 reflect the consistent and complete information available for all participants in the medical records. Data that were incomplete or unavailable for some participants were excluded to ensure the integrity and reliability of our analysis. Specifically, as outlined in the Materials and Methods section of the manuscript, we excluded cases with incomplete medical records to maintain consistency across the dataset. This approach allowed us to focus on parameters that were uniformly documented and avoid potential biases or inaccuracies stemming from missing data.

Discussion:
1- please brief the text in order to focus on your findings of other authors on the result part one by one .Accordingly this part may become more oriented to your results.

Answer: Done. The brief explanation of the results was added to the discussion part.

Acknowledgement:
Please give the name of your coworkers if it is appreciated

Answer: Done. It was added.

Best Regards

Reviewer 2:
Dear author, please consider below comments:

Comment 1: Please report the frequency percentage in the tables in addition to the frequency.

Answer: Done. The frequency percentage was added.

Comment 2: Mark significant variables in tables with a symbol such as an asterisk.

Answer: Done. The significant variables were bolded in the tables.

Comment 3: in line 126, you stated that "mortality rates were high …" please explain in your manuscript that how did you compute mortality rates in each group?

Answer: Done. The explanation was added.

Comment 4: In statistical analysis part, you stated that " to check continuous data, linear models were applied" did you report the results of linear models? Please explain more about it.

Answer: Linear models were applied to analyze continuous data (such as maternal age, Apgar scores, and neonatal outcomes). The results of these linear models, including estimates, confidence intervals, and p-values, were reported to evaluate the impact of maternal COVID-19 infection on various continuous outcomes. Specifically, the linear models helped identify significant differences between the case and control groups for variables such as maternal age and neonatal Apgar scores. Results from these models are presented in the Results section (Tables 1-4), where continuous variables were assessed and compared between groups.

Comment 4: did you use multiple linear regression model in your study?

Answer: Linear models were applied to analyze continuous data; however, multiple linear regression was not used in this study. The analysis focused on simple comparisons between case and control groups, without the inclusion of multiple covariates in a single regression model.

Reviewer 3:
major review

Associate Editor's Comments:

Associate Editor 1:
dear author
thank you for submitting your valuable manuscript. based on our review it needs major revision.
best regard

Reviewer Assistant Comments:

These comments were generated by AI based on your manuscript. Please review them and consider incorporating the suggestions to enhance your article.

Based on the provided case-control study text regarding adverse neonatal outcomes associated with COVID-19, I will apply the STROBE-case-control checklist to assess the study's adherence to reporting guidelines.

STROBE-case-control Checklist Review

1. **Title and Abstract**
    - **Title**: The title indicates the study design as a case-control study.
    - **Abstract**: The abstract provides a balanced summary of the study's objectives, methods, results, and conclusions.
2. **Introduction**
    - **Background/Rationale**: The study presents the background on COVID-19 and its potential impact on maternal and neonatal outcomes.
    - **Objectives**: The specific objectives of the study are clearly stated.
3. **Methods**
    - **Study Design**: The study design is presented early in the paper.
    - **Setting**: The setting is described, including the location and relevant dates of data collection.
    - **Eligibility Criteria**: The eligibility criteria for participants are defined, including the methods of case ascertainment and control selection.
    - **Outcomes**: All outcomes, exposures, predictors, potential confounders, and effect modifiers are clearly defined.
    - **Data Sources/Measurement**: Sources of data and methods of assessment are described.
    - **Bias**: Efforts to address potential sources of bias are mentioned.
    - **Study Size**: The study size is stated, but further explanation on how it was determined could enhance clarity.
    - **Statistical Methods**: Statistical methods used to control for confounding are described.
4. **Results**
    - **Participants**: The number of individuals at each stage of the study is reported, but a flow diagram could enhance clarity.
    - **Descriptive Data**: Characteristics of study participants are provided, including demographic and clinical information.
    - **Outcome Data**: Numbers in each exposure category are reported, but additional detail on missing data would be beneficial.
    - **Main Results**: Unadjusted and adjusted estimates are provided, along with their precision.
5. **Discussion**
    - **Key Results**: Key results are summarized with reference to study objectives.
    - **Limitations**: Limitations of the study are discussed, but a more detailed discussion of potential biases could be included.
    - **Interpretation**: The interpretation of results is cautious and considers limitations.
    - **Generalisability**: The generalisability of the study results is discussed.
6. **Other Information**
    - **Funding**: The source of funding is not mentioned, which should be included.

Summary of Findings

The study adheres well to the STROBE guidelines for case-control studies, with most essential elements reported. However, there are areas for improvement, particularly in providing more detailed explanations of study size determination, addressing missing data, and including funding sources.

Recommendations

- Include a flow diagram to illustrate participant flow through the study.

  Answer: Thank you for your valuable suggestion. Unfortunately, due to limitations in the manuscript's format or software constraints, we are unable to include a flow diagram at this time. However, we have described the participant selection process in detail within the manuscript, outlining the number of women considered, the inclusion and exclusion criteria, and the final number of participants in both the case and control groups. We hope this detailed description provides sufficient clarity regarding the participant flow.

- Provide more detail on how the study size was determined.

  Answer: The study size was determined based on the number of pregnant women admitted to the maternity ward of Ali-Ibn-Abi-Taleb Hospital, Zahedan, Iran, during the study period. We used a convenience sampling method, aiming to include all eligible pregnant women with a documented history of COVID-19 infection during pregnancy in the case group. The control group was matched for age, type of delivery, and parity, consisting of 90 women without COVID-19 infection. Given the total number of eligible cases during the study period, the final sample size was set at 180 participants (90 cases and 90 controls). The sample size was not determined through statistical power calculations but was based on available participants within the inclusion criteria during the study timeframe. All these data are presented in method section.

- Discuss any missing data and how it was handled.

  Answer: Missing data were carefully addressed in our study. For any missing data from the medical records, efforts were made to contact the mothers directly and obtain the required information. In cases where this was not possible, the data were considered missing and were excluded from the respective analysis. No imputation techniques were used for handling missing data.

- Mention the source of funding for the study.

  Answer: This study did not receive any external funding and the research was conducted without specific financial support, which it is mentioned at the end of the manuscript.

2 Revision 1

1 comment · 8 Feb 2025

Referee 1 Reviewer

MINOR REVISION 8 Feb 2025

dear author
Thank you for your submission.
1-Include a flow diagram to illustrate participant flow through the study.
2- Introduction:
- Please don't give the results in this part; only your main objective can be stated and described in this part.
3- Material and Method:
-Provide more detail on how the study size was determined.
-Discuss any missing data and how they were handled.
-Please use this reference "https://doi.org/10.5812/apid-150381" if possible to provide more information from Iran.
Best regards

3

Revision 2

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Editor,

I sincerely appreciate the time and effort you and the reviewers have dedicated to evaluating our manuscript. Your insightful and constructive feedback has been instrumental in enhancing the quality of our work.

We have carefully considered and addressed all the reviewers' comments, making the necessary revisions accordingly. The modified sections have been highlighted in blue for easy reference. Below, we provide a detailed response to each point raised.

We hope that the revised manuscript meets your expectations. Thank you once again for your time and consideration.

Sincerely,
Maryam Razavi

Reviewer 1:
thanks for applying my comments, please consider below comments:

Comment 1: in statistical analysis part, you stated that " to check the continuous data, linear models were applied", please explain about this sentence. Where did you use independent samples T-test and Mann Whitney, and where did you use linear models?

Answer: Thank you for your valuable comment. We have revised the statistical analysis section for clarity. (page 4- line 110-114)

Comment 2: how did you determine sample size in each group of your study, please explain more about it.

Answer: The sample size was determined based on the total number of eligible medical records available within the study period at Ali-Ibn-Abi-Taleb Hospital. We included all available cases of pregnant women with confirmed COVID-19 who met our inclusion criteria (n=90). A matched control group (n=90) was selected based on age, parity, and delivery type to ensure comparability. We have now provided this explanation in the revised Materials and Methods section. (page 4- line 101-107)

Comment 3: Please report the frequency percentage for all variables in the tables in addition to the frequency.

Answer: Thank you for your suggestion. We have now updated all tables to include both absolute frequencies (n) and percentages (%) for each variable.

Reviewer 2:

dear author

Thank you for submission

1-Include a flow diagram to illustrate participant flow through the study.

Answer: A flow diagram has been added to the manuscript to visually represent the participant selection process, including inclusion and exclusion criteria. (Figure 1)

2- Introduction:

- Pls don't give the results in this part , only your main objective can be stated and described in this part .

Answer: The Introduction section has been revised accordingly. Any mention of results has been removed, and the section now focuses only on the study background, rationale, and objectives.

3- Material and Method:

-Provide more detail on how the study size was determined.

Answer: We have expanded the explanation of the sample size determination method. The selection was based on the total number of eligible medical records within the specified study period. Details have been added to the Materials and Methods section. (page 4- line 101-107)

-Discuss any missing data and how it was handled.

Answer: Missing data was addressed by contacting patients directly when possible. If the data remained incomplete, the case was excluded from the study. This information has been explicitly stated in the Materials and Methods section. (page 4- line 96-100)

-plz use this reference " https://doi.org/10.5812/apid-150381" if possible to give more information from Iran.

Answer: Thank you for the suggested reference. We have reviewed and incorporated relevant information from this source into the manuscript. The citation has been added accordingly. (page9- line 251-256)

3 Revision 2

1 comment · 16 Apr 2025

Referee 1 Reviewer

ACCEPT 16 Apr 2025

Dear Author
Thank you for your submission.
This article is accepted. Please explain how you calculated the sample size.
Best Regards