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OPEN PEER REVIEW

Clinical Characteristics and Outcome of Neonates Born to SARS-CoV2 Positive Mothers: An Observation Study from a Single Center in South India

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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

3 comments · 9 Feb 2021 – 5 Apr 2021

Associate Editor

MAJOR REVISION 9 Feb 2021

Dear author
The purpose of the study should be consistent with its methodology. The objective should be defined in such a way that the reason for grouping the study population can be easily understood. In this article, the purpose of the study is not clearly stated. The reader of the article does not understand the purpose of the article until the end of the method section and must guess the purpose of the study from the results of the article. This indicates a methodological dissociation in the presentation of the study report.
The “statistical analysis” section should also be written based on the methodological principles of the study. The variables and outcomes to be analyzed must be specified in the "Method" section.
Regards

Naeeme Taslimi Taleghani Reviewer

MINOR REVISION 5 Apr 2021

Thanks to the authors of the article
This is an interesting paper. However, it needs to be slightly modified. In my opinion, there are a number of strengths and weaknesses in your article.
I think the strengths of your article include the following:
1- The “Title” indicates the study’s design with a commonly used term.
2- The “Abstract” provides an informative and balanced summary of what was done and what was found.
3- The “Introduction” explains the scientific background.
4- The “results” are well written, concise, and useful.
I have some recommendations for you:

1- It is better not to start the sentence with a number.
2- Keywords are not compatible with MESH.

3- Mention in the method section: “How did you make sure that babies who did not return after two weeks were asymptomatic?”

4- Please describe any efforts to address potential sources of bias in “Method”.

5- What is the meaning of this sentence in the Discussion: “The increased number of asymptomatic CoV-19 pregnant women may be due to effective drugs and the patient being young with strong immunity”?

6- Discuss the limitations of the study and the direction and magnitude of any potential bias in “Discussion”.

Referee 1 Reviewer

MAJOR REVISION 5 Apr 2021

Dear AUTHOR
Thank you for submitting your article.
Totally:
This is a study of SARS-COV infection in symptomatic and non-symptomatic pregnant women and their neonates. The study is well organized, but the material and methods do not match the results. The discussion should be reviewed to better compare the results with those of other studies. Please include information from

other articles from outside India.
Abstract:
Results: Please give the most important results, for example, the PCR results. Conclusion: You described the PCR results without providing this information in the results section.
Please omit unnecessary information to reduce the abstract to 250 words.
Material and methods: What are the characteristics of pregnant women with suspected COVID-19? The author stated that information on different parameters was gathered, but some of the results are not shown in the results section (for example, radiologic and laboratory characteristics). Please ensure that the information in the material and methods section matches the results section.
How did the author obtain patient information through communication? (Is this a reliable method for obtaining correct information?)
Which company's RT-PCR kit T was used, and how were samples collected from patients?
Please give the ethical code.
No results are presented as mean and SD or median and IQR in this article.
Results: Please omit the subheadings and arrange the article's format according to the instructions for authors.
Discussion:
The discussion is well organized, but because of the different results reported in the results section, it is recommended that each important result be checked individually and compared with the literature.
This is an observational study; please check with your statistical advisor. Please don't describe the study method in the discussion section. In this sentence, " The increased number of asymptomatic CoV-19 pregnant women may be due to effective drugs and the patient being young with strong immunity", what are the effective drugs used by pregnant women?
The author attributed the negative PCR test results in neonates to isolation, based on this sentence: " This may be due to strict infection control and prevention procedures that were implemented during delivery and the infants were separated immediately from infected mothers, could be the possible explanation", but there is no description of this strategy in the material and methods section.
Conclusion:
Please don't repeat the results in the conclusion section; instead, give your judgment about the results and your recommendations for further studies.
Tables: Please explain the abbreviations used in the tables, for example, PIH/PE, APH, …
Table 1 is incomplete in the last column.
Table 3: It is obvious that symptomatic mothers have more cough than asymptomatic mothers.
Best regards

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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.

Reply to the reviewers' comments

Thank you very much for your valuable comments. As per your suggestions, we have answered all your questions and made the appropriate corrections in the manuscript. We hope our responses meet with your approval.

Reviewer Number	Original comments of the reviewer	Reply by the author(s)	Changes done on page number and line number
Reviewer 1			
Totally	This is a study on pregnant women and their neonates on SARS COV2 infection in symptomatic and non-symptomatic mothers. The study is good arranged but the material and method does not match with results. The discussion should be overlooked for better comparison of results with other studies. Please include information from other articles out of India.	Thanks for this suggestions. As suggested by the reviewer, now the materials method is modified to match the results. Also the discussion section is modified by including the studies from outside India and results discussions.	Materials and method section Page no: 3 Discussion section Page no: 8- 9
Abstract	Results: please give the most important results for example the PCR results. Conclusion: you described the PCR results without giving information in the result part. Please omit the unnecessary information to 250 words.	Now the abstract- results and conclusions are modified as recommended by the reviewer. Also now the abstract is to 230 words.	Abstract section Page no: 1
Question No:1	Material and methods: what are the characteristics of suspected pregnant woman to covid19? The author declared about gathering information from different parameters but some of their results are	The demographic details, clinical manifestations and risk factors of the pregnant women are presented in Table 1. Laboratory characteristics like RT-	Materials and method section Page no: 3,4,5

	not shown in the results part (for example radiological and laboratory characteristics). Please match the information obtained in the materials and methods part with the results part.	PCR result of the pregnant women as test positive or test negative is represented. “laboratory and radiological characteristics” typographical error. Now this sentence is removed from the manuscript. Now information obtained in the method is matched with the results.	
Question No:2	How did the author get the information of patients by communication (is this a reliable method for getting correct information?)	Direct communication with the patient and the attenders is a reliable method of getting information in the hospital. The follow up information was obtained by telephonic conversation and video consultation of the neonates. During the current pandemic it is a reliable method for getting the correct information. Now this information is added in under the materials and method section	Page no: 4, second paragraph Line no: 10
Question No:3	What was the RT PCR kit from which company and what was the method of sampling in patients?	SARS COV2 was tested by qualitative Reverse Transcription polymerase chain reaction nucleic acid detection kit (NeoDx, Biotech labs) Now this kit name is also included in the methods section.	Materials method section Page no:3, line no:8
Question No:4	Please give the ethical code	IEC: MSRMC/EC/AP-01/12-2020	Materials method

			section Page no:3, line no:8
Question No:5	There are no results shown by mean and SD or median IQR in the article	Age, gestational age, birth weight, discharge weight, WBC, platelet and APGAR results are given in mean ± SD	Table 1,2,3 and 4
Results	Please omit the subheadings and arrange the article format based on author information part.	Now the sub heading in the result section is removed as per the reviewer suggestions. To maintain the journal format.	Results section Page no:6
Discussion	Discussion has a good design but because of different results declared in results, it is recommended to check each important result one by one and compare it with literature.	Thanks for this suggestions Now the results are discussed in the discussion section comparing with the other studies conducted in globally.	Discussion section page no: 8-9
Question	Please don't give study method in discussion part. In this sentence "the increased number of asymptomatic cov 19 pregnant women may be due to effective drugs and the patient being young with strong immunity" what are the effective drugs used by pregnant women?	This information was taken from an article quoted. It was a case report from China where a pregnant woman was treated after delivery with antiviral drugs like Arbidol, Lopinavir, Ritonavir and Interferon α2b with good effects. But currently there are no specific antiviral drugs against SARS COV2 virus and the antiviral agents may have teratogenic effect on the fetus. Most of our patients	Discussion section Page no: 8 Line no: 14

		were treated with conventional symptomatic treatment. Since there is no sufficient data available to support this statement, we removed from manuscript	
Question	The author described the reason for negative PCR test of neonate by isolation based on this sentence “this may be due to strict infection control and prevention procedures that were implemented during delivery and the infants were separated immediately from infected mothers, could be the possible explanation” but there is no description of this strategy in material and method part.	Strict COVID infection control policy was implemented in the hospital. Pregnant women who tested positive for SARS COV2 virus were isolated and delivered in isolation labor room and operating theatres. There was no negative pressure room available at our center. Enhanced droplet precautions with the use of non-sterile gloves, gown, standard N95 mask, eye protection was used by all health care workers. Neonates were isolated in nursery/ NICU based on clinical condition of the baby. Baby was feed with expressed breast milk and discharged with a healthy care taker (not a primary contact) and further followed up with teleconsultation.	-

Conclusion	Please don’t repeat the results in conclusion part, instead give your judgement about results and recommend your opinion for further studies.	Now the conclusion part is modified.	Conclusion section Page no: 10 Line no: 6
	Tables: please give the abbreviation information for tables. Table 1 is not complete in last column. Table 3: it is obvious that symptomatic mothers have more cough in comparison with asymptomatic mothers.	The incomplete column in table 1 is removed. Table 3: it is obvious that symptomatic mothers have more cough in comparison with asymptomatic mothers Yes. We agree with the reviewer comment. However, we just collected the data therefore analyzed.	Table 1 Last two column removed.
Reviewer 2			
Question No:1	Keywords are not compatible with MESH	Covid-19; SARS-CoV-2; Pregnancy; Newborn	Now the key words are included
Question No:2	Mention in the method section. How did you make sure that babies who did not return after 2 weeks were asymptomatic?	Parents were contacted over telephone at 2 weeks of age and the status of the neonate was enquired over the telephonic conversation. Video consultation was done whenever necessary.	Page no: 4, second paragraph Line no: 10
Question No:3	Please describe any efforts to address potential sources of bias in methods	When the data collection more than two scientist are involved without knowing	-

		each other. Results are repeated analysis was done by the statistical person.	
Question No:4	What is the meaning of this sentence in the discussion “the increased number of asymptomatic cov 19 pregnant women may be due to effective drugs and the patient being young and strong immunity	It was a case report from China where a pregnant woman was treated after delivery with antiviral drugs like Arbidol, Lopinavir, Ritonavir and Interferon α2b with good effects. But currently there are no specific antiviral drugs against SARS COV2 virus and the antiviral agents may have teratogenic effect on the fetus. Most of our patients were treated with conventional symptomatic treatment.	-
Question No:5	Discuss limitations of the study, direction, and magnitude of any potential bias in discussion.	Now the limitations of this study and future directions are included in the conclusion part.	Conclusion section Page no:10

2 Revision 1

2 comments · 16 Jul 2021 – 5 Sep 2021

Referee 1 Reviewer

MINOR REVISION 16 Jul 2021

Dear author:
Thank you for submitting the article “Clinical characteristics and outcome of neonates born to SARS-CoV2 positive mothers: an observation study from a single center in South India”.
Totally:
This is a valuable study. The results are well arranged, but the variables noted in the material and method section do not match the variables in the tables. English editing is recommended.
Abstract:
The abstract states that pregnant women were divided into two groups: symptomatic and asymptomatic. However, the statistical analysis compared the positive and negative groups. Please add the results of the analysis comparing the symptomatic and asymptomatic groups, if possible.
Introduction:
- Please update the information about the death rate in India.
Material and Method:
- Not all the variables noted in this part are mentioned in the tables. It is recommended that the variables mentioned in this part and in the tables match.
- Are the maternal variables mentioned laboratory findings?
Discussion:
- In this sentence, “The estimated incidence of hospitalization with symptomatic SARS-CoV-2 was 2.0 per 1000 maternities and for asymptomatic SARS-CoV-2 was 1.2 per 1000 maternities”, what was the reason for hospitalization of asymptomatic cases?
- It would be better to move the limitations of the study to the discussion section.
Conclusion:
- The conclusion may contain the basic results and recommendations for further studies.
Best regards

Referee 2 Reviewer

ACCEPT 5 Sep 2021

Thank you for the revisions.

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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.

We humbly thank the reviewer for raising key concerns in the article and helping to improve the quality of the manuscript. We have incorporated all the improvements in the revised manuscript, and we strongly believe that the revised version would be more suitable to publish in your esteemed journal. The incorporated changes are marked with yellow highlighted. Responses to the reviewer's comments are enumerated below, and appropriate changes have been made in the revised manuscript. As per the reviewer’s suggestion, the grammar errors have been rectified in the revised manuscript.

REVIEWER #1:

Reviewer 1:

Dear author:

Thank you for submission of “Clinical characteristics and outcome of neonates born to SARS-CoV2 positive mothers: an observation study from a single center in South India” article

Totally:

Question: This is a valuable study. The results are well arranged but the variables noted in material and method part does not match with the variable in tables. English edition is recommended.

Answer: The variable mentioned in methods sections are; age, Preterm prolong rupture of membranes, Gestational diabetes mellitus, Pregnancy induced hypertension /pre eclampsia, Antepartum hemorrhage. Further, the maternal characteristics such as cough, PPROM, GDM, PIH/PE and APH and for neonatesbirth weight, mode of delivery, CPAP, MV, surfactants,WBC count, platelet count and C reactive protein.

The same was mentioned in Table 1, 2, 3 and 4. Also the same was discussed in the discussion section as recommended by the reviewer.

Question: Abstract:

In abstract its declared that pregnant woman was divided in to two symptomatic and asymptomatic groups. but the statistical analysis was between positive and negative groups.plz add the the results of analysis between symptomatic and asymptomatic groups if possible.?

Answer:

Thank you very much for this valuable comments. The results of analysis between symptomatic and asymptomatic groups was added under the result section and highlighted.

Question: Introduction:

- Please upgrade the information about death rate in india.

Answer:

As suggested by the reviewer, now the updated data on death rate in India added under the introduction section.

The statement as it follows,

Furthermore, a recent systematic review found that maternal deaths increased by 37% during the SARS-CoV-2 pandemic compared with the pre-pandemic period (12). However, only two studies from India reported the significant increase of maternal deaths. One study found a 7% increase in maternal deaths (13), but the other did not find an increase during the pandemic compared with the pre-pandemic period (14).

Question: Material and Method:

- All Variables noted in this part are not mentioned in tables. It is recommended to match the variables mentioned in this part and tables

Answer: now the variables mentioned in the methods section are added in the tables.

- Are the maternal variables mentioned are laboratory findings?

Answer: Most of the variables are collected from datasheet.

Question: Discussion:

- In this sentence “The estimated incidence of hospitalization with symptomatic SARS-CoV-2 was 2.0 per 1000 maternities and for asymptomatic SARS-CoV-2 was 1.2 per 1000 maternities” what was the reason of hospitalization of asymptomatic cases.

Answer:

According to previous study, the hospitalized women with symptomatic SARS-CoV-2 were more likely to be overweight or obese, to be of Black, Asian or Other minority ethnic group, and to have a relevant medical comorbidity including asthma and hypertension.

The characteristics associated with asymptomatic SARS-CoV2 on hospital admission were Black, Asian or Other minority ethnicity and gestational diabetes.

Question: - Limitation of study is better to move to discussion part.

Answer: As recommended by the reviewer, now the limitation part has been moved to discussion part.

Question Conclusion:

- Conclusion may contain the basic results and recommendations for further studies.

Answer:

As suggested by the reviewer, the conclusion part is modified.

We hope our responses meet with your approval for possible publication.

Thank you

3 Revision 2

1 comment · 2 Nov 2021

Referee 1 Reviewer

MINOR REVISION 2 Nov 2021

Dear author
Thank you for submitting the manuscript.
There are a few notes:
Introduction:
Please provide the address in the references section for the first sentence in the Introduction.
Many words are written without spaces, for example, "thetransmission"… Please correct them.
Best regards

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Revision 3

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.

We humbly thank the reviewer for raising key concerns in the article and helping to improve the quality of the manuscript. We have incorporated all the improvements in the revised manuscript, and we strongly believe that the revised version would be more suitable to publish in your esteemed journal. Responses to the reviewer's comments are enumerated below, and appropriate changes have been made in the revised manuscript.

REVIEWER #1:

Reviewer 1:

Question: Please give the address in the references section from the first sentence in introduction.

Answer: As suggested, now the address for the first sentence was added in the reference section (Reference No: 1)

Question:

There are many words that are written without space for example thetranmission and …..plz correct them

Answer: as recommended by the reviewer, now the words written without space are corrected throughout the manuscript.

We hope our responses meet with your approval for possible publication.

Thank you

4 Revision 3

0 comments

No public comments in this round.