

OBSTETRICS & GYNECOLOGY



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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)*

**The corresponding author has opted to make this information publicly available.*

Personal or nonessential information may be redacted at the editor's discretion.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:
obgyn@greenjournal.org.

Date: Jun 06, 2022
To: "Alexandra Jade Loza" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-963

RE: Manuscript Number ONG-22-963

Short-term pregnancy outcomes following Paxlovid treatment for mild to moderate COVID-19: initial report.

Dear Dr. Loza:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for fast track consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 7 days from the date of this letter. If we have not heard from you by Jun 13, 2022, we will assume you wish to withdraw the manuscript from further consideration.

EDITOR COMMENTS:

It is not necessary to add a control group. It is OK to keep this as a case series.

REVIEWER COMMENTS:

Reviewer #1:

This is a case series of 7 patients who received paxlovid in pregnancy, 6 of whom were vaccinated. All patients did well clinically with no apparent complications or adverse events.

Introduction
—no comments

Methods
Line 19-20 - please confirm the dates - is it meant to be listed in the reverse order ?

Lines 23-25 - can you be specific about if vaccinated patients were also considered candidates for paxlovid ? (I see in the results the answer is yes but might be nice to include here as this is a big question that comes up clinically)

Lines 23-25 - were monoclonal Ab or IV remdesivir (3 day outpatient regimen) also available to these patients ? If so , how did clinicians select who was a candidate for remdesivir vs mAB vs paxlovid ? Did patients with other comorbidities get other treatments - which would make we wonder if these 7 patients were going to do well regardless of paxlovid rx.

Lines 25-26 - can you provide more details about types of questions asked / when asked/ what and how data collected ? Maybe a phone survey was administered ? If so please include instrument .

Lines 28-31 - how long were patients followed after paxlovid use, for assessing the adverse events ? Was follow up complete ? What adverse events did you include in your review ? Did you also assess for paxlovid rebound ? Please specify as this is of clinical importance in the current climate

Results

Line 36 - since you only have 7 patients perhaps a little more data on the spread of GAs treated would be useful - mean GA/SD or # (%) per trimester ? I didn't expect a 9w4d patients nor that 3/7 would have been delivered with a mean GA of 26 weeks.

Lines 40-41 - do you have any data on # of days to symptom resolution - mean/SD or median/IQR ? Everyone's COVID symptoms resolve eventually. But knowing how quickly it resolves with paxlovid in preg is useful clinical data for patient counseling

Discussion

—line 52 - in this case series it seems all had symptoms resolution (either due to natural history or paxlovid) - not most

—line 54 - what fetal effects were surveilled for ? This isn't previously discussed

Table -

—can you include the vaccine status of the patients here ?

—the last patient in the table also appears to have obesity

Reviewer #2: ONG 22-963

In this research letter, we review a case series reporting on the effects of the use of Paxlovid for the treatment of mild to moderate COVID-19 infection during pregnancy. The authors gathered data from 7 patients and concluded that most had no adverse effects from the treatment and experienced symptom resolution.

A few comments on the manuscript are as follows:

1. Introduction - no major issues identified. A clear objective is laid out.
2. Line 19-20 please provide an explanation for choosing this timeline.
3. Was this limited to patients that presented to the ER seeking medical care? Patients seen in an outpatient clinic? Where were patients counseled on treatment?
4. Was treatment offered to all pregnant women with a positive COVID-19 swab?
5. What dosing was used? Length of treatment?
6. Line 34-37 how many patients were offered treatment? How many refused?
7. Do the authors have any data on placental pathology from the cases that have delivered?
8. Discussion - The statement on symptom resolution needs to be modified. Since this study cohort lacks a control group, it is very difficult to attribute symptom resolution to treatment rather than normal evolution of the disease. Have the authors considered reporting the outcomes of patients with mild to moderate disease during the same study period that didn't receive Paxlovid and using them as controls? This would strengthen the report and add validity to the conclusions.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

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:

* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at

the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.

- * 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's Copyright Transfer Agreement (CTA) must be completed by all authors. When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

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, describe the reasons that race and ethnicity were assessed in the Methods section and/or in table footnotes. Race and 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.

List racial and ethnic categories in tables in alphabetic order. Do not use "Other" as a category; use "None of the above" instead.

Please refer to "Reporting Race and Ethnicity in Obstetrics & Gynecology" at https://edmgr.ovid.com/ong/accounts/Race_and_Ethnicity.pdf.

5. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "Patients with obesity" instead of "obese patients," "Women with disabilities" instead of "disabled women," "women with HIV" instead of "HIV-positive women," "women who are blind" instead of "blind women."

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:

CHEERS: economic evaluations of health interventions

CHERRIES: studies reporting results of Internet e-surveys

CONSERVE: reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances

CONSORT: randomized controlled trials

MOOSE: meta-analyses and systematic reviews of observational studies

PRISMA: meta-analyses and systematic reviews of randomized controlled trials

PRISMA for harms: PRISMA for harms

RECORD: observational studies using ICD-10 data

STARD: studies of diagnostic accuracy

STROBE: observational studies

SQUIRE 2.0: quality improvement in health care studies

Include the appropriate checklist for your manuscript type upon submission, if applicable, and indicate in your cover letter which guideline you have followed. 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 www.equator-network.org/.

7. 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.

8. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Research Letters: 600 words (do not include more than two figures and/or tables [2 items total])

9. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

- * 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.
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10. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make 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 manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Research Letter: 125 words

11. 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.

12. The journal does not use the virgule symbol (/) in sentences with words, except with ratios. 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.

13. 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.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001").

Express all percentages to one decimal place (for example, 11.1%). Do not use whole numbers for percentages.

14. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available at http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

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Please make sure your references are numbered in order of appearance in the text.

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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 a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

If you submit a revision, we will assume that it has been developed in consultation with your coauthors and that each author has given approval to the final form of the revision.

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jun 13, 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

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Alexandra J. Loza
263 Farmington Ave.
Farmington, CT 06030
[REDACTED]

Re: Research Letter Submission

Dear Editorial Board,

On behalf of my co-authors, I am pleased to submit our revised manuscript titled “Short-term pregnancy outcomes following Paxlovid treatment for mild to moderate COVID-19: initial report.” for consideration for publication as a Research Letter in *Obstetrics & Gynecology*. Each author participated actively in revising sections based on reviewer comments. We have no conflicts of interest related to this work. Our work has institutional review board approval from University of Connecticut Health Center.

I affirm that this manuscript is an honest, accurate, and transparent account of the cases being reported. If you have any questions about the revised manuscript, I will be serving as the corresponding author. Thank you for your consideration.

I, Alexandra Loza, have reviewed and edited the submission to omit any identifying information. I hereby submit this self-blinded manuscript for consideration in *Obstetrics & Gynecology*.

Thank you for your consideration.

Sincerely,

Alexandra Loza, DO

Alexandra J. Loza, DO
Maternal Fetal Medicine Fellow, PGY6
University of Connecticut Health Center

EDITOR COMMENTS:

It is not necessary to add a control group. It is OK to keep this as a case series.

[REDACTED]

-The manuscript was left as a case series. A control group was not added.

REVIEWER COMMENTS:

Reviewer #1:

This is a case series of 7 patients who received paxlovid in pregnancy, 6 of whom were vaccinated. All patients did well clinically with no apparent complications or adverse events.

Introduction

—no comments

Methods

Line 19-20 - please confirm the dates - is it meant to be listed in the reverse order?

-Dates have been confirmed and changed to April 16, 2022 through May 18, 2022 in the manuscript (lines 19-20).

Lines 23-25 - can you be specific about if vaccinated patients were also considered candidates for paxlovid ? (I see in the results the answer is yes but might be nice to include here as this is a big question that comes up clinically)

-Both vaccinated and unvaccinated patients who met criteria as outlined in lines 21-27 received Paxlovid treatment. This clarifying statement was included in the manuscript (lines 27-29).

Lines 23-25 - were monoclonal Ab or IV remdesivir (3 day outpatient regimen) also available to these patients ? If so, how did clinicians select who was a candidate for remdesivir vs mAB vs paxlovid ? Did patients with other comorbidities get other treatments - which would make we wonder if these 7 patients were going to do well regardless of paxlovid rx.

-During our study time frame, monoclonal Abs were available to our patients as an alternative treatment if patients declined treatment with Paxlovid or had a contraindication to Paxlovid treatment. This was the recommended treatment protocol advised by our infectious disease specialists during our study time frame. At our institution, IV remdesivir was reserved for hospitalized patients with severe COVID-19.

From Dec 1, 2021 through mid-March, we reviewed pregnancy outcomes for twenty-one pregnant patients with mild to moderate COVID-19 who received IV monoclonal antibodies during the Omicron surge. Comorbidities in these patients included obesity, chronic hypertension, and diabetes mellitus. We found similar findings in that most patients who received mAb treatment experienced symptom resolution without the need for additional care. One patient experienced an anaphylactic reaction during monoclonal antibody treatment, otherwise mAB infusion was tolerated by the twenty other patients without immediate adverse effects.

The authors do not feel that the aforementioned information needs to be added to the manuscript, because we were specifically looking at short term outcomes in patients who received Paxlovid treatment.

Lines 25-26 - can you provide more details about types of questions asked / when asked/ what and how data collected ? Maybe a phone survey was administered ? If so please include instrument

In regards to follow up, once our nurse received a call that a patient tested positive, the patient was contacted within minutes to hours of receiving the call.

The following questions were asked:

1. When did you test positive for Covid?
2. When did your symptoms start?
3. What symptoms are you experiencing?
4. Are you vaccinated? Did you receive a booster?
5. Are you interested in speaking with a provider regarding the risks/benefits of Paxlovid?

On day 8-10 after symptom onset, our nurse contacted patients to inquire how they are feeling and if they completed the Paxlovid course if it was prescribed for them. Questions asked included:

1. Are you experiencing any lingering Covid symptoms? If so, what symptoms are you experiencing?
2. Have your symptoms improved since day 1?
3. Did you start Paxlovid? If so, did you complete the course?
4. After completing Paxlovid, do you feel like it helped you recover more quickly/resolve your symptoms?
5. Why did you not take Paxlovid/finish the course if it was ordered for you?

- Common answers included that they started feeling better/symptoms were mild so they decided they didn't need to take Paxlovid. One patient reported strong metallic taste that discouraged them from completing the course of Paxlovid. One patient stated her pharmacy was delayed on filling the script so by the time it was ready her symptoms were resolving.

The information gathered from the above was placed into an excel spreadsheet. The remainder of the study data was gathered by reviewing the patient's medical chart in our electronic database.

The time frame from when a patient experienced symptoms of COVID-19 to when our nursing staff made contact was described in the manuscript. Due to word count limit, the specific questions were not included in text form as the pertinent information gathered is reflected in the Table.

Lines 28-31 - how long were patients followed after paxlovid use, for assessing the adverse events? Was follow up complete? What adverse events did you include in your review? Did you also assess for paxlovid rebound? Please specify as this is of clinical importance in the current climate

Patients were followed for the remainder of their pregnancy and if delivered, through the immediate postpartum period (line 35). At present, four patients remain pregnant with resolution of COVID-19 without additional pregnancy complications. We plan to complete their follow up.

We did not specifically assess for Paxlovid rebound, however, we contacted patients to assess for symptom resolution, ongoing symptoms, or new symptoms of COVID-19 8-10 days following symptom onset. All patients in our study reported symptom resolution within this time frame. Further, these patients were seen for ongoing ultrasounds, and per review of medical records, it does not appear that our study patients experienced rebound symptoms. This is reflected in the statement "All patients experienced symptom resolution without the need for additional care related to COVID-19" which is stated in the original manuscript.



Results

Line 36 - since you only have 7 patients perhaps a little more data on the spread of GAs treated would be useful - mean GA/SD or # (%) per trimester ? I didn't expect a 9w4d patients nor that 3/7 would have been delivered with a mean GA of 26 weeks.

The three patients that delivered at term were diagnosed with COVID at 34+1, 37+3, and 36+0. Four patients remain pregnant at this time. The average time from symptom onset to treatment was approximately 2 days and the average gestational age at time of treatment was 26 weeks and 3 days with SD \pm 11. This information is presented in Table 1.

Lines 40-41 - do you have any data on # of days to symptom resolution - mean/SD or median/IQR ? Everyone's COVID symptoms resolve eventually. But knowing how quickly it resolves with paxlovid in preg is useful clinical data for patient counseling

Patients were contacted 8-10 days following symptoms onset to assess for symptom resolution. All patients in our study experienced symptom resolution within this time frame. We have included this time frame as a reference to better clarify this for the readers (line 29 and 52-53 respectively).

Discussion

—line 52 - in this case series it seems all had symptom resolution (either due to natural history or paxlovid) - not most

This statement was revised in the manuscript as follows, "This case series describes short-term outcomes in seven pregnant patients with COVID-19 who received Paxlovid treatment, demonstrating that all patients receiving Paxlovid treatment experienced symptom resolution without the need for additional care." (lines 72-74).

—line 54 - what fetal effects were surveilled for ? This isn't previously discussed

-We surveilled for congenital anomalies, fetal growth restriction, and stillbirth along with birth outcomes including weight, APGARS, and need for NICU admission. Due to word count limit, the a statement was added to the Table to include both pregnancy complications and neonatal complications surveilled for.

Table -

—can you include the vaccine status of the patients here ?

-Please see revised table. Vaccine status added.

—the last patient in the table also appears to have obesity

- We have listed obesity as a comorbidity for this patient.

In this research letter, we review a case series reporting on the effects of the use of Paxlovid for the treatment of mild to moderate COVID-19 infection during pregnancy. The authors gathered data from 7 patients and concluded that most had no adverse effects from the treatment and experienced symptom resolution.

A few comments on the manuscript are as follows:

1. Introduction - no major issues identified. A clear objective is laid out.
2. Line 19-20 please provide an explanation for choosing this timeline.

-This timeline was chosen because Paxlovid was first prescribed starting in mid-March in our practice setting. The manuscript was modified to reflect this (line 20).

3. Was this limited to patients that presented to the ER seeking medical care? Patients seen in an outpatient clinic? Where were patients counseled on treatment?

-This study included pregnant patients receiving obstetric care at UConn Health. Patients either sought care in the emergency setting or contacted their provider with symptoms of COVID-19 or known diagnosis for further instruction. Patients with known diagnosis of COVID-19 were then called by a provider for counseling on Paxlovid treatment and to ensure they were appropriate candidates. Please see lines 39-42 addressing this question.

4. Was treatment offered to all pregnant women with a positive COVID-19 swab?

-Yes, so long as they had mild to moderate disease, had no contraindications to Paxlovid treatment and symptom onset occurred within the past 5 days. Please see lines 39-42.

5. What dosing was used? Length of treatment?

-See lines 41-42 of revised manuscript. Paxlovid (300mg nirmatrelvir with 100mg ritonavir orally twice daily for five days)

6. Line 34-37 how many patients were offered treatment? How many refused?

- During the study time frame, eleven patients receiving obstetric or emergency care at UConn Health were identified as candidates for Paxlovid treatment. All patients were accepting of a Paxlovid prescription following counseling by a provider; however, four patients did not initiate treatment. See lines 39-43 of revised manuscript.

7. Do the authors have any data on placental pathology from the cases that have delivered?

-We do not have this information for the patients that are currently delivered. Due to word count limit, the authors do not feel that this needs to be stated in the manuscript.

8. Discussion - The statement on symptom resolution needs to be modified. Since this study cohort lacks a control group, it is very difficult to attribute symptom resolution to treatment rather than normal evolution of the disease. Have the authors considered reporting the outcomes of patients with mild to moderate disease



during the same study period that didn'tt receive Paxlovid and using them as controls? This would strengthen the report and add validity to the conclusions.

Per the editorial comments, we plan to leave this study as a case series. We can certainly identify a control group as suggested to strengthen our study for future publication once all data has been collected on our Paxlovid cohort. Thank you for the recommendation.