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OPEN PEER REVIEW

Real-life Data of Glecaprevir/Pibrentasvir in Chronic Hepatitis C Patients: A Single-center Study

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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 · 5 Mar 2023 – 8 Mar 2023

Referee 1 Reviewer

MINOR REVISION 5 Mar 2023

The study is within the scope of the journal, as it concerns infectious liver diseases.
The title of the work reflects the topic pretty well. No abbreviations are present in the title. The study brings new insights regarding SVR rates during DDAs treatment in a cohort of chronically HCV-infected Turkish patients in a real-life setting. The abstract is well structured. The word count is correct according to journal requirements. The keywords section contains appropriate terms. The aim of the study is clearly stated. The lack of data regarding SVR rates in HCV-infected Turkish patients treated with GLE/PIB justifies the rationale for this study. The selection of patients is clearly explained; still, the cohort is not very large. The inclusion/exclusion criteria are well stated. The retrospective study provides a comprehensive analysis of the patients included in the study. The statistics package is correctly chosen and brings accurate results. Results are clear and well illustrated in figures and tables. They appear in a logical sequence in the tables and figures. There are no duplicates. The discussion section presents extensive data from the literature regarding the issue and makes feasible comparisons with the current results, emphasizing their value. Conclusions are very clear and follow from the results section. The references are appropriate to the topic, all from the last 5 years. The authors state the limitations of the study very well.

Associate Editor

MINOR REVISION 8 Mar 2023

The authors reported the treatment outcome among 92 patients with HCV who received GLE/PIB therapy. Although the data have limited novelty, the paper can still contribute to the literature given the limited regional data. I have several relatively minor comments outlined below:
1. Abstract (Methods): Please clarify that out of 116 patients, 92 were included in the analysis.
2. Abstract (Results): The authors are encouraged to report the findings (where applicable) as XX% (n=XX). In the current reporting style, it is not clear what the numbers in parentheses are referring to.
3. Background, line 34: “more than 70 million people are thought to be infected with HCV”. A more recent estimate of the HCV population is available. Look at: https://doi.org/10.1016/S2468-1253(21)00472-6
4. Methods, line 66-67: “patients followed by the Infectious Diseases and Clinical Microbiology clinic between March 2019 and December 2021 were included in the study”. More details about this clinic would be useful. For example, what geographical area is it located in? What services are provided? Is this a referral center? How representative are the HCV patients?
5. Methods, line 71: Please report the lower limit of detection for the HCV RNA assay used in the study.
6. Methods, line 73: HCV12 has been defined as “the absence of HCV viral load 12 weeks after completion of DAA therapy”. I was wondering if the authors meant “undetectable” or “unquantifiable” HCV RNA by “the absence of HCV viral load”.
7. Methods, line 75: “Detection of HCV RNA in serum after the first four weeks of treatment was defined as early virological response (EVR)”. I was wondering if the authors meant “undetected HCV RNA” (not “Detection of HCV RNA”).
8. Methods, line 79. Please correct the spelling of “intention to treat (ITT)”.
9. Methods, line 90. “This study was conducted with the approval of XXX”. Please clearly state the ethics committee that approved the study protocol.
10. Results: I was wondering what the distribution of HCV risk factors among participants was, e.g., how many people were injecting drugs.

11. Results: Please report the duration of treatment in the study population, e.g., how many were started on 8, 12, and 16 weeks of treatment. Please also report the data on treatment adherence (if available).
12. Figure 1 included artifacts. Please submit a clear version of the figure.

Editor-in-Chief MINOR REVISION 8 Mar 2023

Dear Authors,

Please follow the peer-review comments and submit a revision.

Regards,
EIC

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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.

March 18, 2023

Dear Dr. Kamran Bagheri Lankarani

Editor-in-Chief

Hepatitis Monthly

Dear Dr. Kamran Bagheri Lankarani

Subject: Submission of revised paper ID: 134406, Real-Life Data of Glecaprevir/Pibrentasvir in Chronic Hepatitis C

We would like to thank you for the letter dated 08/03/2023, and the opportunity to resubmit a revised copy of this manuscript. We would also like to take this opportunity to express our thanks to the reviewers for the positive feedback and helpful comments for correction or modification.

We have carefully reviewed the comments and have revised the manuscript accordingly. The revision has been developed in consultation with all coauthors, and each author has given approval to the final form of this revision.

Following this letter are reviewer comments with our responses how and where the text was changed is in bold.

We look forward to hearing from you in due time regarding our submission and to respond to any further questions and comments you may have.

Sincerely,

Reviewer 1:

The study is between the scopes of the journal, referring to liver infectious diseases. The title of the work reflects pretty well the topic. No abbreviations are present in the title. The study bring new insights regarding SVR rates during DDAs treatment in a chronically HCV infected Turkish cohort of patients in a real-life setting. The abstract is well structured. The words counting is correct according to journal requirements. The keywords section contains the proper affirmations. The aim of the study is clearly stated. The missing data regarding SVR rates in HCV infected Turkish patients treated with GLE/PIB are justifying the rationale of this study. The selection of patients is clearly explained; still the cohort is not so big. The inclusion/exclusion criteria are well stated. The retrospective study makes a comprehensive analyze of the patients included in the study. The statistics package is correctly chosen and bring accurate results. Results are clear and well illustrated in figures and tables. They come in a logical sequence in the tables and figures. There are no duplicates. The discussion section comes with a vast literature data regarding the issue and make feasible comparisons with the current results, emphasizing their value. Conclusions are very clear and they result from the results section. The references are appropriate to the topic, all from the last 5 yrs. The authors state very well the limitations of the study.

We *thank you* to the reviewers for the positive feedback and helpful comments

Reviewer 2: *The authors reported the treatment outcome among 92 patients with HCV received GLE/PIB therapy. Although the data have limited novelty, the paper can still contribute to the literature given limited regional data. I have several relatively minor comment outlined below:*

1.Abstract (Methods): Please clarify that out of 116 patients, 92 were included in the analysis.

We agree with the reviewer and have changed the information about the study.

Of the 116 patients included in the study, 92 were analyzed. It has been added to the Abstract (Methods) section and written in bold.

2. Abstract (Results): The authors are suggested to report the findings (where applicable) as XX% (n=XX). In the current reporting style, it is not clear what the numbers in parentheses are referring to.

We agree with the reviewer, all text has been corrected as suggested and written in bold.

3. Background, line 34: "more than 70 million people are thought to be infected with HCV". More recent estimate of HCV population is available. Look at: https://doi.org/10.1016/S2468-1253(21)00472-6

We agree with the reviewer, Background, line 34: rewritten per reviewer recommendation and source updated.

4. Methods, line 66-67: "patients followed by the Infectious Diseases and Clinical Microbiology clinic between March 2019 and December 2021 were included in the study". More details about this clinic would be useful. For example, what geographical area it is located in? What services provided? Is this a referral centre? How representative HCV patients are?

We agree with the reviewer, *Methods, line 66-67:* written per reviewer recommendation. Hatay is a province of Turkey in the Mediterranean Region with coasts at the eastern end of the Mediterranean Sea. This is a referral center that is the only center providing HCV treatment in the Hatay region.

5. Methods, line 71: Please report the lower limit of detection for HCV RNA assay used in the study.

We agree with the reviewer, has been corrected as suggested and written in bold. The lower detection limit of the HCV RNA assay kit was 50 copies/ml

6. Methods, line 73: HCV12 has been defined as "the absence of HCV viral load 12 weeks after completion of DAA therapy". I was wondering if the authors meant "undetectable" or unquantifiable" HCV RNA by "the absence of HCV viral load".

By "absence of HCV viral load" is meant "undetectable" or "unmeasurable" HCV RNA

7. Methods, line 75: "Detection of HCV RNA in serum after the first four weeks of treatment was defined as early virological response (EVR)". I was wondering if the authors meant "undetected HCV RNA" (not "Detection of HCV RNA").

We mean "undetected HCV RNA"

8. Methods, line 79. Please correct spelling of "intention to treat (ITT)".

We agree with the reviewer, has been corrected as suggested and written in bold.

9. Methods, line 90. "This study was conducted with the approval of XXX". Please clearly state the ethics committee who approved the study protocol.

We agree with the reviewer, has been corrected as suggested and written in bold.

10. Results: I was wondering what the distribution of HCV risk factor among participants was, e.g., how many people were injecting drugs

This requested information has been added to line 110 of the study. In this study, 40.2% (n=37) of the patients had a history of substance use and almost all of these patients had a history of IV drug use. Has been corrected as suggested and written in bold.

11. Results: Please report the duration of treatment in the study population, e.g. how many were initiated on 8, 12, and 16 weeks treatment. Please also report the data of treatment adherence (if available)

We agree with the reviewer, has been corrected as suggested and written in bold. This study is the first real-life data in our region, and although it was during the Covid-19 pandemic, high SVR-12 was obtained in patients with HCV. Three patients who had previously been treated with NS5A received treatment for 16 weeks, and 89 patients for 8 weeks. No patient was treated for 12 weeks.

12. Figure 1 included artifacts. Please submit a clear version of the figure.

We agree with the reviewer, *Figure 1 was revised and uploaded in line with the recommendations.*

2 Revision 1

2 comments · 27 Mar 2023 – 27 Mar 2023

Associate Editor

ACCEPT 27 Mar 2023

The authors have made the required revisions.

Editor-in-Chief

ACCEPT 27 Mar 2023

Dear Authors,

I am delighted to inform you that your manuscript is accepted for publication in the journal Hepatitis Monthly.

Regards,
EIC