

PEER-REVIEW REPORT

Name of journal: *World Journal of Gastroenterology*

Manuscript NO: 84676

Title: Real-world effectiveness and safety of direct-acting antivirals in hepatitis C virus patients with mental disorders

Provenance and peer review: Invited manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 03731983

Position: Editorial Board

Academic degree: AGAF, DSc, MD, PhD

Professional title: Chief Doctor, Full Professor, Senior Scientist

Reviewer's Country/Territory: Russia

Author's Country/Territory: Poland

Manuscript submission date: 2023-03-23

Reviewer chosen by: AI Technique

Reviewer accepted review: 2023-03-24 06:27

Reviewer performed review: 2023-03-24 10:31

Review time: 4 Hours

Scientific quality	<input type="checkbox"/> Grade A: Excellent <input checked="" type="checkbox"/> Grade B: Very good <input type="checkbox"/> Grade C: Good <input type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
Novelty of this manuscript	<input type="checkbox"/> Grade A: Excellent <input checked="" type="checkbox"/> Grade B: Good <input type="checkbox"/> Grade C: Fair <input type="checkbox"/> Grade D: No novelty
Creativity or innovation of this manuscript	<input type="checkbox"/> Grade A: Excellent <input checked="" type="checkbox"/> Grade B: Good <input type="checkbox"/> Grade C: Fair <input type="checkbox"/> Grade D: No creativity or innovation

Scientific significance of the conclusion in this manuscript	<input type="checkbox"/> Grade A: Excellent <input checked="" type="checkbox"/> Grade B: Good <input type="checkbox"/> Grade C: Fair <input type="checkbox"/> Grade D: No scientific significance
Language quality	<input checked="" type="checkbox"/> Grade A: Priority publishing <input type="checkbox"/> Grade B: Minor language polishing <input type="checkbox"/> Grade C: A great deal of language polishing <input type="checkbox"/> Grade D: Rejection
Conclusion	<input type="checkbox"/> Accept (High priority) <input type="checkbox"/> Accept (General priority) <input checked="" type="checkbox"/> Minor revision <input type="checkbox"/> Major revision <input type="checkbox"/> Rejection
Re-review	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Peer-reviewer statements	Peer-Review: <input type="checkbox"/> Anonymous <input checked="" type="checkbox"/> Onymous
	Conflicts-of-Interest: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

SPECIFIC COMMENTS TO AUTHORS

This is nice retrospective study of the efficacy and tolerability of DAA anti-HCV treatment in patients with mental disorders at country level. Due to scarce data on the efficacy and tolerability of DAA treatment of HCV in patients with mental health disorders and just few full text publications with large cohorts of patients enrolled, this study should be welcomed. Despite of the fact that the appropriate methods used and a quality of the manuscript is good, some points need to be clarified. 1. Authors found that the 16.7% of patients from group A had previously been treated with interferon, however, it is not clear what proportion of this patients did not respond due to premature discontinuation of the treatment due to AE, did all these patients achieve response with DAAs, and what was the rate of AE in them in compare to control? 2. Authors noted higher lost of follow-up rate in group A in comparison to the control, but they did not provide possible explanation or additional analysis, then discussing this fact as a part of the adherence problem, they mentioned 2 publications (Ref.39 and Ref.44), which both are not relevant for this discussion as the first one was performed in psychiatric nursing homes and the second one included patients participated in clinical



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trials with GLE/PIB, other words the adherence in these patients was very well controlled. This study represented data, obtained in a real-world settings, in which adherence was not carefully controlled and difference in the lost of follow-up numbers may be clinically important and indicate to the lower adherence to the treatment. 3. At the page 13 of the manuscript authors said that "To the best of our knowledge, this is the first study to address the problem of treating chronic hepatitis C in patients with mental disorders, highlighting the differences in specific psychiatric illnesses." Unfortunately, it is not true as in 2022 excellent analysis of the efficacy of HCV treatment in mental health disorders patients from 7 countries was published in which such differences were described. (Wedemeyer, H.; et al. Global Real-World Evidence of Sofosbuvir/Velpatasvir as a Highly Effective Treatment and Elimination Tool in People with Hepatitis C Infection Experiencing Mental Health Disorders. *Viruses* 2022, 14, 2493. <https://doi.org/10.3390/v14112493>). Authors should correct discussion section of the manuscript accordingly and discuss their data against the results from this study.

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Reviewer's code: 04737004

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Academic degree: MD, PhD

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Scientific quality	<input type="checkbox"/> Grade A: Excellent <input type="checkbox"/> Grade B: Very good <input checked="" type="checkbox"/> Grade C: Good <input type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
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Re-review	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Peer-reviewer statements	Peer-Review: <input checked="" type="checkbox"/> Anonymous <input type="checkbox"/> Onymous Conflicts-of-Interest: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

SPECIFIC COMMENTS TO AUTHORS

The authors retrospectively assessed the effectiveness and safety of DAA in HCV-infected patients with or without concurrent mental illness. They found that the SVR12 rates by PP analysis were comparable in patients with or without mental illness, while the proportion of patients who were lost-to follow-up was higher in patients with mental illness, compared to those without. Furthermore, the safety profile was comparable between groups.

1. Please indicate clearly all the statistical number throughout the manuscript for those with p values > 0.05. Just state > 0.05 was not acceptable and non-professional.

2. Figure 1B was not clearly demonstrated. What was the comparators in Figure 1B subgroups, e.g. anxiety vs. non-anxiety (in mental illness group) or anxiety vs, non-anxiety (whole group). Please show all the numbers of patients with SVR/index group in the columns in Figures 1A and 1B.

3. The authors should show in the details of the univariate analysis, with an assumption of cut-off p value (such as < 0.10) set by the authors to enter multivariate analysis. To sum up, re-do the Table 4 to show the details of uni- and multi-variate analyses. Just show the multivariate analysis subjectively was not acceptable. Furthermore, re-organize the statistical wordings in the

text accordingly. 4. The authors should show the potential drug-drug interaction profiles before the initiation of DAA therapy, e.g. how many patients adjusted or switched mental illness co-medications before DAAs. How many patients were treated with DAAs who also were on co-medications which were considered contraindicated for use? Please add a supplementary summary Table to show the detailed information of patients who had switch or termination of co-medication (particularly mental ill-related drugs) before being treated with DAAs, in group A and B patients. 5. Figure 5: The information was not clear. What did it mean Tx discontinuation? Also what did it mean Tx modification? Did the authors mean discontinuation or dose modification of DAA or co-medications or both? What was the proportion of patients who resumed Tx after discontinuation? Conventionally, the dose of DAA should not be modified. If Tx modification indicated DAA dose modification, it seemed violation to label recommendation. 6. The abstract should clearly defined ITT and PP analyses in Methods, and should show the SVR12 rates with ITT and PP forms. Please show the switch or termination of co-medications in each group in the abstract.