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PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology

Manuscript NO: 48171

Title: Effects of Dual Sofosbuvir/Daclatasvir Therapy on, Chronic Hepatitis C Infected, Survivors of Childhood Malignancy

Reviewer's code: 01488602

Reviewer's country: Romania

Science editor: Jia-Ping Yan

Reviewer accepted review: 2019-04-10 04:17

Reviewer performed review: 2019-04-10 04:22

Review time: 1 Hour

SCIENTIFIC QUALITY	LANGUAGE QUALITY	CONCLUSION	PEER-REVIEWER STATEMENTS
[ ] Grade A: Excellent [ ] Grade B: Very good [Y] Grade C: Good [ ] Grade D: Fair [ ] Grade E: Do not publish	[ ] Grade A: Priority publishing [Y] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection	[ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [ ] Major revision [Y] Rejection	Peer-Review: [Y] Anonymous [ ] Onymous Peer-reviewer's expertise on the topic of the manuscript: [ ] Advanced [Y] General [ ] No expertise Conflicts-of-Interest: [ ] Yes [Y] No

SPECIFIC COMMENTS TO AUTHORS

This is a correct study but the degree of novelty seems reduced; a controlled study at the beginning would have been more convincing; the results were those to be expected from the beginning of the study,

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INITIAL REVIEW OF THE MANUSCRIPT

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[ ] No

REPLY 1:

Regarding the reduced novelty: It is well known that up to the moment of submission of this manuscript, there has been no PANGENOTYPIC direct acting antiviral therapy (DAA) approved for pediatric groups less than 18 years of age.
Sofosbuvir/Ledipasvir (SOF/LDV) as well known is not approved for genotype 2 or 3 (SEE SLIDES Below).
Even the latest EASL guidelines recommend against the use of SOF/LDV for treatment experienced patients.
The latest WHO guidelines recommended the use of a PANGENOTYPIC combination for the treatment of hepatitis C infection rather than a gene-specific combination (such as SOF/LDV) (SEE SLIDE Below)

This study tested the safety and efficacy of a PANGENOTYPIC combination (SOF/DCV) (which will provide a new hope for children infected with genotype 2 and 3 for which the latest EASL guidelines stated that they should not be treated with SOF/Ribavirin but they better be treated with a PANGENOTYPIC regimen accepted

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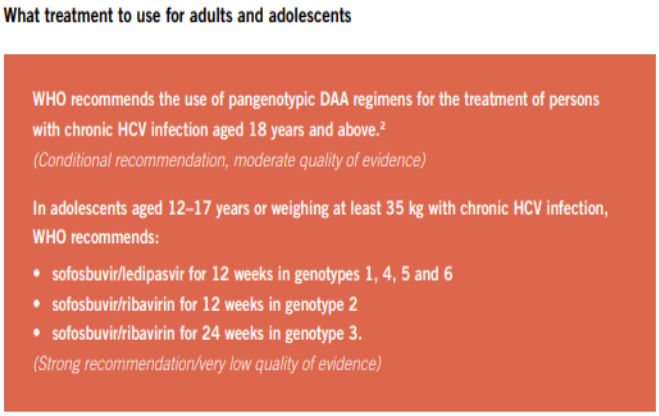
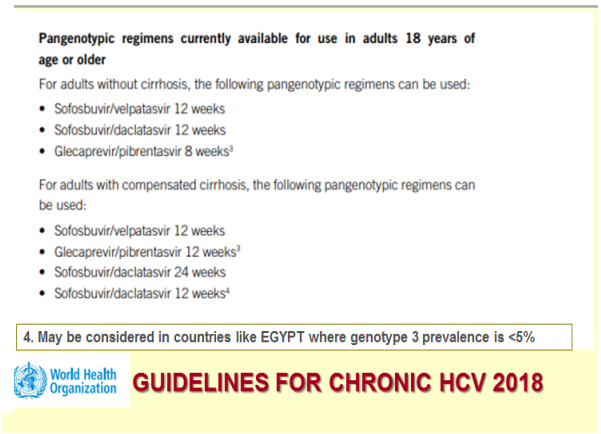
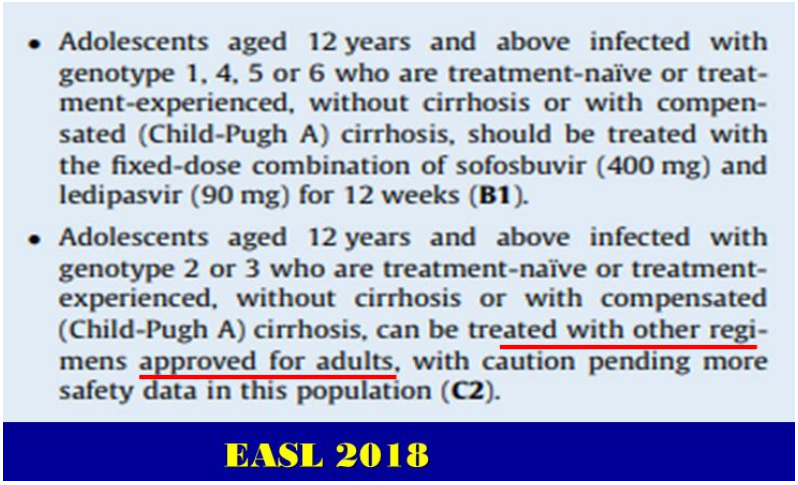
for adults, pending studies like ours that prove safety and efficacy in such age group (SEE SLIDE 3).

Also, this is the first study ever to address very critical research question (not addressed before in pediatric age group) which is still making a lot of worries among treating physicians with conflicting data (does treatment with DAAs affect remission from malignancy .... We all know that many data from adult studies for survivors of hepatocellular carcinoma suggest that DAAs treatment could be associated with a rapid reactivation of HCC with more aggressive course. No other studies in pediatric age group addressed this critical research question, and our study is the first to take this challenge and to reassure pediatricians that treatment with DAAs will not adversely affect this vulnerable subset of poor patients infected with chronic HCV.







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Name of journal: World Journal of Gastroenterology

Manuscript NO: 48171

Title: Effects of Dual Sofosbuvir/Daclatasvir Therapy on, Chronic Hepatitis C Infected, Survivors of Childhood Malignancy

Reviewer's code: 02541859

Reviewer's country: United States

Science editor: Jia-Ping Yan

Reviewer accepted review: 2019-04-12 13:20

Reviewer performed review: 2019-04-12 13:56

Review time: 1 Hour

SCIENTIFIC QUALITY	LANGUAGE QUALITY	CONCLUSION	PEER-REVIEWER STATEMENTS
[ ] Grade A: Excellent [ ] Grade B: Very good [Y] Grade C: Good [ ] Grade D: Fair [ ] Grade E: Do not publish	[ ] Grade A: Priority publishing [Y] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection	[ ] Accept (High priority) [ ] Accept (General priority) [Y] Minor revision [ ] Major revision [ ] Rejection	Peer-Review: [Y] Anonymous [ ] Onymous Peer-reviewer's expertise on the topic of the manuscript: [Y] Advanced [ ] General [ ] No expertise Conflicts-of-Interest: [ ] Yes [Y] No

SPECIFIC COMMENTS TO AUTHORS

This ia good study on HCV GT4 infection in children with hematological malignancies. As the fibroscan cut off was 12.5 kp. all the study patients were non-cirrhotic. So I think the title should changed to non-cirrhotic HCV GT-4 infected patients.

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REPLY 2:

We opted not to have a very lengthy title; particularly because the main focus of this study was not to measure the efficacy of therapy on the virus, but to explore cautiously the effect of this treatment on a special vulnerable subset of patients (pediatric cancer survivors) (NOVELTY).

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PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology

Manuscript NO: 48171

Title: Effects of Dual Sofosbuvir/Daclatasvir Therapy on, Chronic Hepatitis C Infected, Survivors of Childhood Malignancy

Reviewer's code: 02687374

Reviewer's country: China

Science editor: Jia-Ping Yan

Reviewer accepted review: 2019-04-11 06:54

Reviewer performed review: 2019-04-19 02:58

Review time: 7 Days and 20 Hours

SCIENTIFIC QUALITY	LANGUAGE QUALITY	CONCLUSION	PEER-REVIEWER STATEMENTS
[ ] Grade A: Excellent [ ] Grade B: Very good [Y] Grade C: Good [ ] Grade D: Fair [ ] Grade E: Do not publish	[Y] Grade A: Priority publishing [ ] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection	[ ] Accept (High priority) [ ] Accept (General priority) [Y] Minor revision [ ] Major revision [ ] Rejection	Peer-Review: [Y] Anonymous [ ] Onymous Peer-reviewer's expertise on the topic of the manuscript: [Y] Advanced [ ] General [ ] No expertise Conflicts-of-Interest: [ ] Yes [Y] No

SPECIFIC COMMENTS TO AUTHORS

This clinical prospective study was testing the effects of dual sofosbuvir/daclatasvir (SOF/DCV) therapy in the treatment of chronic HCV in survivors of hematologic malignancy in pediatric age group. As we all know, dual sofosbuvir/daclatasvir are

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effective drugs for the treatment of HCV. In this study, the authors used dual sofosbuvir/daclatasvir to treat a particular population and achieved satisfactory results. One of the biggest shortcomings of this study maybe the small number of research crowd and the short duration of follow-up. In addition, introduction to the overall efficacy of dual sofosbuvir/daclatasvir in the treatment of HCV at this stage was not observed in this manuscript, and it is recommended to supplement the discussion if necessary. The research crowd is all infected with HCV genetype-4, is it still effective in the treatment of other HCV genotypes?

INITIAL REVIEW OF THE MANUSCRIPT

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REPLY 3:

We did acknowledge the limitations in our study in discussion, and we gave the reasons for this which is the vulnerable nature of the study population (cancer survivors in pediatric age group), this study is the first to address this critical research

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question in such vulnerable group of patients. We have to approach this area very cautiously (given that the association of DAAs with early reactivation of hepatocellular carcinoma is still an issue not fully resolved.

This combination was chosen by authors as it is PANGENOTYPIC, and the all latest guidelines recommend the use of PANGENOTYPIC if possible, that would be of value to facilitate the process of mass treatment and WHO project of elimination of viral hepatitis by the year 2030.

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PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology

Manuscript NO: 48171

Title: Effects of Dual Sofosbuvir/Daclatasvir Therapy on, Chronic Hepatitis C Infected, Survivors of Childhood Malignancy

Reviewer's code: 00070845

Reviewer's country: United States

Science editor: Jia-Ping Yan

Reviewer accepted review: 2019-04-17 02:18

Reviewer performed review: 2019-04-29 03:16

Review time: 12 Days

SCIENTIFIC QUALITY	LANGUAGE QUALITY	CONCLUSION	PEER-REVIEWER STATEMENTS
[ ] Grade A: Excellent [Y] Grade B: Very good [ ] Grade C: Good [ ] Grade D: Fair [ ] Grade E: Do not publish	[Y] Grade A: Priority publishing [ ] Grade B: Minor language polishing [ ] Grade C: A great deal of language polishing [ ] Grade D: Rejection	[ ] Accept (High priority) [Y] Accept (General priority) [ ] Minor revision [ ] Major revision [ ] Rejection	Peer-Review: [Y] Anonymous [ ] Onymous Peer-reviewer's expertise on the topic of the manuscript: [Y] Advanced [ ] General [ ] No expertise Conflicts-of-Interest: [ ] Yes [Y] No

SPECIFIC COMMENTS TO AUTHORS

Discuss the reasons that patients with probable cirrhosis (FibroScan .12.5, APRI > 2, etc.) were excluded from the study since they had the most to benefit

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REPLY 4:

The reason for exclusion criteria in this study and in clinical trials in general is to provide a rather homogeneous study group and not to risk a vulnerable group, taking in consideration that this dual therapy is not yet accepted by FDA, EMA or other drug authority as a line of therapy for less than 18 years old.