Author’s response to reviews

Title: Efficacy and tolerability of sofosbuvir and daclatasvir for treatment of hepatitis C genotype 1 & 3 in patients undergoing hemodialysis- A prospective interventional clinical trial

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Author’s response to reviews:

Response to Required Changes:
BNEP-D-19-00295R2

Efficacy and tolerability of Sofosbuvir and Daclatasvir for treatment of Hepatitis C genotype 3 in patients undergoing hemodialysis- A Prospective interventional clinical Trial
Shafiq Ur Rehman Cheema; Muhammad Salman Rehman; Ghulam Hussain ; Sidra Shafiq Cheema; Nooman Gilani BMC Nephrology

Dear Prof. Dr. Cheema,

Your manuscript "Efficacy and tolerability of Sofosbuvir and Daclatasvir for treatment of Hepatitis C genotype 3 in patients undergoing hemodialysis- A Prospective interventional clinical Trial" (BNEP-D-19-00295R2) has been assessed by our reviewers. They have raised a number of points which we believe would improve the manuscript and may allow a revised version to be published in BMC Nephrology.

Their reports, together with any other comments, are below. Please also take a moment to check our website at https://www.editorialmanager.com/bnep/ for any additional comments that were saved as attachments. Please note that as BMC Nephrology has a policy of open peer review, you will be able to see the names of the reviewers.

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Please also ensure that your revised manuscript conforms to the journal style, which can be found at the Submission Guidelines on the journal homepage.

A decision will be made once we have received your revised manuscript, which we expect by 18 Sep 2019.

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I look forward to receiving your revised manuscript and please do not hesitate to contact us if you have any questions.

Best wishes,

Robin L. Cassady-Cain, PhD
BMC Nephrology
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Editor Comments:
Please go over your background, results, discussion and conclusions sections and ensure they are written in original language. They currently have an unacceptable overlap in text with previously published sources.
Response: Taken care & currently plagiarism is near to 0.0% and original/unique language is used.

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Reviewer reports:
Masanori Atsukawa (Reviewer 1): This article by Shafig Ur Rehman Cheema et al, assessed that the efficacy and safety of SOF/DCV regimen in patients on hemodialysis and they recommended full dose of SOF for patients regardless of ESRD state. Although this manuscript is well written, the reviewer considers that there are some critical concerns which should be clarified and corrected.

Major points
First off, nowadays, IFN-free DAA regimens were widely recommended for patients with or without renal impairment. Actually, guideline in several country and region were well known; e.g. AASLD, EASL, JSH and APASL. However, the patients with severe renal impairment were recommended to use DAAs other than SOF based regimen as author described. In clinical practice, many reports described the efficacy and safety of DAAs for chronic hepatitis patients with ESRD. GT1 patients for Elbasvir and Grazoprevir or Daclatasvir and Asunaprevir or Paritaprevir and Ombitasvir with retonavir, GT2 patients for Glecaprevir and Piblentasvir and GT1-6 patients for Glecaprevir and Piblentasvir have been already published.


So, authors should cite these articles and describe the priority of SOF based regimen compared to other regimens described above in Introduction or Discussion section.

Especially, patients with GT3 were all achieved SVR in this study. It was reported that SVR rate were lower in patients with GT3 in Phase 3 trials. So, this result is a strongest point in this study. Author should discuss about this point. To my knowledge, Gane E et al. (NEJM 201) reported the result of GP treatment in patients with GT3.

Response: Discussion relevant to Genotype 3 is mentioned under Discussion section, Page 12 (Highlighted).

Meghan E. Sise (Reviewer 2): The authors present a trial comparing two dosing schemes of sofosbuvir-based (SOF-DAC) therapy for dialysis patients.

1. You cannot exclude patients because they were noncompliant. Must analyze as intention to treat. May also perform a "modified intention to treat" but the primary analysis should be intention to treat. Throughout the results the denominator needs to remain 18 for group 1 and 18 in group 2, not removing these patients who were not compliant or stopped bc of adverse events.

Response: The data was not included in the analysis, as these patients were withdrawn from the study for specified reason and no further data could be gathered from these study participants as per study protocol. Patients did not complete even 2 weeks period and refused to participate in the study after
initial enrollment.

2. Add to table comparing baseline characteristics in each group (gender, diabetes status)
Response: Gender related information included in the table-1, Page 8.

3. can then remove much of the text in the beginning of the results and refer to Table 1.
Response: Information is made bit concise now, Page 6.

4. This study includes patients with genotypes 1 and 3. The title should be changed
Response: Study Title edited.

5. Discussion should mention trials of elbasvir and grazoprevir and glecaprevir and pibrentasvir as these are important to note as not renally excreted and studied in large prospective trials, even though they may not be available in all parts of the world
Response: Studies, trials now cited in Discussion section for the specified drugs (references added).

If improvements to the English language within your manuscript have been requested, you should have your manuscript reviewed by someone who is fluent in English. If you would like professional help in revising this manuscript, you can use any reputable English language editing service. We can recommend our affiliates Nature Research Editing Service (http://bit.ly/NRES_BS) and American Journal Experts (http://bit.ly/AJE_BS) for help with English usage. Please note that use of an editing service is neither a requirement nor a guarantee of publication. Free assistance is available from our English language tutorial (https://www.springer.com/gb/authors-editors/authorandreviewertutorials/writinginenglish) and our Writing resources (http://www.biomedcentral.com/getpublished/writing-resources). These cover common mistakes that occur when writing in English.

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