Reviewer’s report

Title: Real World Experience of Patients with Amyotrophic Lateral Sclerosis (ALS) in the Treatment of Spasticity using Tetrahydrocannabinol:Cannabidiol (THC:CBD)

Version: 0 Date: 10 Jun 2019

Reviewer: Susana Pinto

Reviewer's report:

After reading your work I have the following major considerations:

- How was ALS diagnosis made (in Methods, under Participants) and how many patients had spinal and bulbar onset form?

- Were the patients doing other anti-spastic medication or had done it? Had the patients done botulinum toxin?

- Out of the 68 patients, 24 (more than 1/3) did not want to participate in the study (questionnaire) and were excluded. Had those patients started the medication? If so, how would you say the clinical efficacy of the drug was? By not including those patients you can be introducing an important bias to your results, specially if those patients were non-responders.

- Can you clarify why the Ashworth modified scale was not used? Why is the presence of lower limb symptoms (weakness) a limitation of the scale if it should be assessed passively? How can you adequately classify spasticity in mild, moderate, severe? Was it assessed always by the same evaluators?

- How could patients perceive spasticity - during gait, for example? How was it explained to them? Was it correlated with the neurologists´ own perception/ evaluation of spasticity? A functionality scale could have been included.

- How many patients in your study had only spasticity in the upper limbs (as mentioned by you)? What was their onset form?

- For each patient, was the amount of daily dose constant over the 4-mo course? When were the scales done? When a 7 consecutive-day period with the same dosage was reached? What happened thereafter?

- It is really not clear if the patients in your retrospective study did a max of 20 applications per day or 12. Can you please clarify? What side effects, if any, did you encounter? Did any patients discontinue the medication?
- How can you warranty that the perception of spasticity amelioration was indeed not simply a diminishing on the pain level?

- Were TSQM-9 and NPS correlated?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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Please indicate the quality of language in the manuscript:

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