Author’s response to reviews

Title: OBSERVATIONAL STUDY OF PATIENTS IN SPAIN WITH AMYOTROPHIC LATERAL SCLEROSIS: CORRELATIONS BETWEEN CLINICAL STATUS, QUALITY OF LIFE, AND DIGNITY

Authors:

Yolanda Martínez-Campo (yolandamartinezcampo@gmail.com)
Christian Homedes (christianhomedes@gmail.com)
Ana Lázaro (alarfe@hotmail.com)
Raquel Alarcón (Raquel.alarcon.cano@gmail.com)
David Campo (davidcampo19@gmail.com)
Mariona Riera (marionarieral@gmail.com)
Raúl Domínguez (rauldominguez@gmail.com)
Mónica Povedano (mpovedano@ballvitgehospital.cat)
Carlos Casasnovas Pons (carloscasasnovas@bellvitgehospital.cat)

Version: 3 Date: 30 Oct 2017

Author’s response to reviews:

Dear Sirs,

In reference to the manuscript PCAR-D-17-00093 entitled “OBSERVATIONAL STUDY OF PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS IN SPAIN: CORRELATIONS BETWEEN CLINICAL STATUS, QUALITY OF LIFE AND DIGNITY” that is being considered for publication in BMC Palliative Care.

Please, find enclosed the detailed response to the editor point raised, describing exactly what amendments has been made to the manuscript text and where these can be viewed.

The present work has not been published and is not being considered for publication elsewhere.

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

No conflict of interest has been declared by the authors.
The study has been conducted in full accordance with the World Medical Association Declaration of Helsinki (2008)

Please find enclosed the answers to the reviewers point by point

Dear Associate Editor:

Abstract

1. A sentence has a word missing ‘We aimed to study the impact of ALS on QoL and DoL and [how] these evolve throughout the duration of the disease’.

The word “how” has been added in the abstract (Line: 9 page 4)

2. First sentence of results in abstract, please say if the significant difference favours the control or the ALS group. The last two sentences in this same paragraph are not clear. First you say there was a significant difference in QOL from baseline to three months and then you say there was no significant difference. I think you have a missing word, DoL, in the second sentence?

The word DoL has been added, now the sentence, and in fact, the entire paragraph has its real meaning (Line 22 Page 4)

3. Please add to conclusions ‘our findings are limited by small sample sizes’. Your results do not as you conclude suggest that DoL may be an important target in the management, but if you state in the methods that the patients you recruited were from a specialist ALS unit then this conclusion would make more sense?

The changes have been made in Abstract conclusions (Line: 22-3 Page: 5) and abstract methods (Line: 12 page: 4)

Background

4. The following new sentence is misplaced in the background, please add it appropriately to your methods.

‘The ALS unit of our center (UFELA) manages patients with ALS from the Catalonia region, but mainly sees patients from our hospital’s immediate catchment of approximately 1.3 million people’.

The sentence has been placed in methods (Line: 18-20 Page: 9)
5. The following sentences provide some clarity on what the study is about:

‘In the first part of this two-step study, we aimed to determine how ALS affects QoL and DoL in comparison with healthy controls. In the second part, we prospectively studied how the clinical evolution of ALS affects DoL and QoL. To the best of our knowledge, no study in Spain has explored the potential value of maintaining high QoL and DoL in a severe neurodegenerative disease that lacks effective treatment’.

But I would not consider that you are exploring the potential value of maintaining high QoL and DoL, rather you are exploring whether patients from your specialist unit suffer a decline.

The sentences have been clarified (Line: 8-13 Page: 9)

Trial design

6. Can you make it clear whether or not those in the second part of the study where involved in the first part of the study?

The data about the patients in the second part of the study has been clarified (Line: 2 Page: 10)

Assessment tools

7. Last sentence can you say whether you used any of the assessment tools to measure outcomes in the healthy controls.

The tools to measure patients and controls have been added (Lines: 14-16 Page: 10)

Statistical analysis

8. Could you provide some text on the observational study on what outcomes you compared.

The compared outcomes have been added (Lines: 19-20 Page: 10)

Results

9. First study: Please replace average age of patients and controls by mean or median.

The word average has been replaced (Lines: 5 Page: 11)

10. Second study: You provide scores for clinical status and QOL but whilst there may be significant difference in these scores between baseline and follow-up how does the reader know
these are important. For the ALSFR scale does a 3 point change really make a major impact to the patient? For the ALSAQ40 scale you say in the methods that the scale goes up to 200, so would 6-point change much for the patient? Could you discuss these points in your discussion section?

The authors have added in the discussion some points to clarify why the change in 3,7 point in ALSFR and 6 points in ALSAQ40 have a clinical impact in the patients

(Lines: 23-5 Page: 14-15)

Discussion

11. Fourth paragraph, in the first sentence you say your sample was representative can you say why?

The epidemiological findings of the patients were similar to the previous reported studies so, from our point of view, this sample could be considered a representative sample of ALS patients

(Lines: 13-15 Pages: 14)

12. You say in this paragraph that the need for technical aid such as BPAP had a significant and negative association with QOL and DoL, but looking at your results in your text I don’t see this presented.

You are right the missing sentence explaining the statistical significant differences in QoL in patients using PEG and BPAP has been added in results. Now the sentence in discussion has its real meaning

(Lines: 15-16 Page: 11)

13. The next paragraph needs to start by stating you are now discussing the other study you did.

The authors have clarified that in this paragraph we start discussing the prospective study (Line: 23 Page: 14)

14. In new paragraph on limitations you state follow-up is low, this is incorrect. The correct word is short, please amend.

The word low has been replaced by short (Line: 15 Page: 19)
15. The last sentence says you matched controls with patients by age but your results describe them as on average 10 years or so younger, please add this as a limitation. I would suggest a future study should also explore patient’s and their families views on quality and dignity.

The differences in age between controls and patients have been added as a limitation of the study in the discussion.

The authors are taking into account all these limitations in order to design a future study on QoL and DoL in ALS patients with a greater number of patients and a longer period of follow-up.

Definitely, we absolutely agree with the associate editor that adding the family members and caregivers of the patients will enhance this future study.

16. In your next paragraph you talk about ‘general and contemporary management principles’, can you say more about what you are referring to.

Traditional public health management control practices (MCP) include the use of budgeting systems, financial performance measures and reports, and cost-control techniques for decisions. On the other hand contemporary MCP provides a balanced focus on various aspects of health care policies. The balanced scorecard is one of the contemporary MCP most used in public health agencies, which identifies objectives and measures for four different perspectives, one of this perspectives is the customer satisfaction that could include, in case a neurodegenerative disease as ALS, functional scores, quality of life and probably dignity of life (Gostin, L. et al, J. Am. Med. Assoc. 1996; Sahin, Y.G et al, J. Med. Syst. 2012, Weir, E at al, BMC Public Health 2009)

Carlos Casasnovas