Author’s response to reviews

Title: Health-related quality of life as predictor for mortality in patients treated with long-term mechanical ventilation

Authors:
Heidi Markussen (heidi.markussen@helse-bergen.no)
Sverre Lehmann (sverre.lehmann@helse-bergen.no)
Roy Nilsen (Roy.Miodini.Nilsen@hvl.no)
Gerd Natvig (Gerd.Natvig@uib.no)

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Author’s response to reviews:

Cecilia Devoto
Editor
BMC Pulmonary Medicine

Comments to the decision letter concerning manuscript ID: PULM-D-18-00330R1

Title: Health related quality of life as predictor for mortality in patients treated with long-term mechanical ventilation. Heidi Markussen, PhD candidate, Intensive Care Nurse; Sverre Lehmann, MD, Associate Professor; Roy Miodini Nilsen, PhD, Associate Professor; Gerd Karin Natvig, Professor, RN

Dear Cecilia Devoto.

Thank You for sending the reviewers’ responses to our paper. The comments concerning 'Ethics approval and consent to participate' initiated a thorough examination of all study approvals. We identified a mistake concerning 15 of the study participants regarding the written consent to
access comorbidity data from the Norwegian Patient Registry (NPR). Written consent was a prerequisite to allow linking of data between the registries. Exemption was given for cohort patients who died. The reason for not getting the written consent from the 15 patients were, dementia or unable to answer the questionnaire (n=3), had stopped using LTMV (n=8), unable to make contact (n=1) or did not want to respond (n=3). These 15 patients were categorized into the disease groups: neuromuscular disease (n = 6), chronic obstructive pulmonary disease (n = 2), obesity hypoventilation syndrome (n = 6) and chest wall disease (n = 1).

We have now conducted new cox regression analyses excluding the 15 patients from the dataset resulting in minor changes in hazard ratio, with slightly lower levels of significance in some of the analyses. All tables are also revised after excluding these 15 patients, the sample constitute now (n = 112) and the results were minor changes in the descriptive tables. In general, the main results and conclusions of the study are unchanged.

Again, thank You to the editor and the reviewers in BMC pulmonary medicine who made us discover this mistake and hope that the paper still is acceptable for publication in BMC Pulmonary Medicine.

Yours sincerely,

Heidi Markussen
Intensive care nurse, PhD candidate
Department of Thoracic Medicine, Haukeland University Hospital
Department of Global Public Health and Primary Care, University of Bergen
Norway

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Comment from reviewer and editor:

-- If Consent to participate statements are already present within the main text/Methods section, please also copy/place it under the 'Ethics approval and consent to participate' sub-section. Please
also state whether the informed consent obtained was written or verbal. If verbal, please state the reason and whether the ethics committee approved this procedure.

Authors’ response:

Thank you immensely for this comment, which initiated a thorough examination of all study approvals and disclosure of a mistake concerning consent to link comorbidity data from the Norwegian Patient Registry (NPR) in 15 of the patients in the study. The reason for not having the written consent from the 15 patients are described in the letter to the editor.

We have now conducted new cox analyses excluding these 15 patients from the dataset. The HR did not change after analyses (n=112) (Table 4) or in the NMD category (n=48), but with slight lower significance levels in some of the SRI scores (Table 4-6). In the COPD category, there were minor HR changes in two of the SRI subscales (Table 6) resulting in non-significant results according to significant level p < 0.05, changes are marked in red color (See Result section, headline ‘SRI sum and subscales in relation to mortality’ page 12-13). Excluding these 15 patients also lead to minor changes in the mean SRI sum scores in the characteristic variables (Table 1) and a minor changes in the difference of characteristic between survivors and deceased (Table 2). The revised analyses also lead to minor changes in the SRI scores of the surviving LTMV patients and the deceased (Table 3).

Further, we have added information concerning written consent to allow register connection to the Norwegian Patient Registry (See Methods section, line 5, page 7 and line 1-5 page 8). We have also clarified and added information concerning ethics approval and consent to participate (See Declarations, last section, page 19).

Comment from reviewer and editor:

-- We notice that you have mention ‘Figure 1’ within the main text of your manuscript. Please ensure that this figure has been uploaded as a separate file, and provide figure titles/legends under a separate heading of ‘Figure Legends’ after the References.

If you do not wish to include this figure, please remove any reference to it within the text.
Authors’ response:

Thank you for pointing this out. We have ensured that figure 1 has been uploaded as a separate file. We have provided figure titles/legends under a separate heading of ‘Figure Legends’ after the References.

Comment from reviewer and editor:

-- Please also add a section “Supplementary files” where you list the following information about your supplementary material:

- File name
- Title of data
- Description of data

Authors’ response:

We have added a section “Supplementary files” and listed the following information:

File name: Supplemental table 1 and 2.

Supplemental table 1. Correlation between baseline scores (both sum score and subscales) of the Severe Respiratory Insufficiency questionnaire and respiratory variables in 112 patients treated with long-term mechanical ventilation between 2008 and 2014.

Supplemental table 2. Hazard ratios for mortality by baseline scores (both sum score and subscales) of the Severe Respiratory Insufficiency questionnaire in obesity hypoventilation syndrome patients (n=32) treated with long-term mechanical ventilation between 2008 and 2014.

Comment from reviewer and editor:

Please ensure that all additional files are explicitly referred to in the main text.
Authors’ response:

We have ensured that all additional files are explicitly referred to in the main text.

Comment from reviewer and editor:

-- We note that you have included a ‘Consent for publication’ section in the Declarations. Consent for publication refers to consent for the publication of identifying images or other personal or clinical details of participants that compromise anonymity. Seeing as this is not applicable to your manuscript please state “Not Applicable” in this section.

Authors’ response:

We have stated “Not Applicable” in the ‘Consent for publication’ section.

Comment from reviewer and editor:

--Please include a Keywords section below your abstract listing three to ten keywords representing the main content of the article.

Authors’ response:

Thank you for pointing this out. We have included a Keywords section below the abstract and added the following keywords: Long-term mechanical ventilation, health-related quality of life, predictors, mortality, survival, The Severe Respiratory Insufficiency (SRI) questionnaire.

Comment from reviewer and editor:

-- In the section 'Funding', please also describe the role of the funding body/bodies in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.
Authors’ response:

We have described the role of the funding body/bodies in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Comment from reviewer and editor:

-- At this stage, please upload your manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colours. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files.

Authors’ response:

Because of the new cox regression analyses and new descriptive analyses after excluding the 15 patients from the sample, we have upload the revised part of the manuscript and tables in red color.

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