Author's response to reviews

Title: Validation of the new COPD Assessment Test (CAT) translated into Thai in patients with Chronic Obstructive Pulmonary Disease (COPD)

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Author's response to reviews: see over
Cover letter

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Dr. Catia Cornacchia
BMC Pulmonary Medicine
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Re: Response to concerns from Dr Arnold

Dear Dr. Cornacchia:

On behalf of co-authors, I am pleased to submit this paper as attached to the BMC Pulmonary Medicine. Please find our responses to the reviewer 's report as follows:

**Major**

**Comment 1** it seems my first major concern was not clearly explained. And your answer doesn't address it. What I meant is that use of scales for clinical routine, i.e. at individual level, needs specific properties and performances to be assessed. A good scale for research, with high reliability, validity and responsiveness, is not always a good scale for use at individual level. Particularly, Cronbach alpha level 0.85 is high for a use of the scale in group comparisons (as you say, > 0.70 is ok for aggregate data), but is low for use of scale to estimate individual levels. The statement "This questionnaire can be used as an easy and reliable tool to assess health status in COPD patients in studies as well as in clinical practice" is supported by data as regards "use in studies", but it is not supported by data as regards "use in clinical practice". The discussion about this point is well conducted, however, one can only encourage the use of the tool in routine, not state that it has shown to be suitable for that purpose. I would like to see a statement expressing the need of further studies to demonstrate its ability to reliably measure intra-individual change, detect interpretable differences to norms, trigger or support useful discussion between patient and doctor, and generally contribute to better and moire efficient care... A sentence such as "Not
only CAT could be used to reflect the health status but also will provide clinicians with the assessment for long-term follow-up of individual patients” is a expressing a wish, not a fact nor a scientific truth. Such sentence needs to be altered a more rigorous statement.

Response: Thank you for your comment. In discussion part was adjusted

- This tool can be used as an easy and reliable tool to assess health status in COPD patients in clinical studies and may be encouraged the use of this tool in routine clinical practice.

- this study provides some evidence that the Thai version of CAT will provide the practicing physician to measure the impact of COPD on health status of their patients with a reliable tool. We need further studies to demonstrate its ability to reliably measure intra-individual change, detect interpretable differences to norms, trigger or support useful discussion between patients and physicians which contribute to better and more efficient care.

Comment 2) in "Methods Health Status questionnaires" section:
- rather than the name of the company preforming the translations, and in addition to the reference to ISPOR guideline, I would like to see a brief description of steps (forward - how many-?, backward?, tests with patients? Contacts with authors?)

Response: Thank you for your comment. In Method; Health status questionnaire part was adjusted

- It was translated into Thai language in accordance with the International Society for Pharmacoeconomics and Outcome Research translation and cultural adaptation process for patient-reported outcomes [13]. The linguistic validation process involved translation of the original English CAT to Thai (forward translation) and retranslation of the Thai CAT to English (back translation). It also included a medical reviewer to check medical language and terminology of the translation to obtain the appropriateness of the expressions in the text as well as a pilot test performed in 10 patients with COPD. The final Thai CAT version was used for validation in this study.

- complete description of CAT content is needed, in place of "The Cat has 8 items and encompassed questions like...".

Response: Thank you for your comment. In Method; Health status questionnaire part was adjusted

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The CAT has 8 items, covering cough, phlegm, chest tightness, breathlessness, activity limitation, confidence, sleep and energy.

Comment 3) In "Results Health status questionnaire Gold stage" section
- We understand that only the comparison of GOLD II and GOLD IV gave significant result. We need to see the global test value (as you show for SGRQ in table 1)

Response: This information has been added in session: Health status questionnaires-GOLD stage “The comparison of mean CAT score and COPD severity stages (GOLD stages) revealed insignificantly different scores (11.3 ± 6.7, 11.2 ± 6.9, 12.5 ± 7.3 and 16.3 ± 8.2 for GOLD I, II, III and IV, respectively, p=0.142)”

- Could we see results according to exacerbations?

Response: We couldn’t see the CAT score change during exacerbation because we we had done only stable COPD patients. We added the missing criteria for inclusion in the method section “They had an established diagnosis of COPD based on post-bronchodilator FEV$_1$/FVC < 0.7 in the past 6 months, were smokers or ex-smokers with a smoking history of more than 10 pack years and had no history of acute exacerbation for at least three months prior to enrollment.

Comment 4 In discussion: we need small differences across GOLD to be discussed in more details with some comparison to other published results. Also, correlation to MRC and SGRQ are not very high. Was it the same with other populations?

Responses: Thank you for your comment. In discussion was adjusted

- We found no significant differences of mean CAT score across different GOLD stages (except GOLD II and IV), this is different from other studies [14, 16, 19]. The reason would be the FEV$_1$ classified by GOLD stages in our study had poorest correlation ($r = -0.193$).

And

- In the present study, we had the opportunity of testing the correlation between CAT and MRC dyspnea score; it was statistically significant with moderate correlation ($r = 0.550$), this is similar to other studies (0.50-0.579) [19, 21, 22]. We added reference number 21 and 22.
Minor

Comment 1) May I suggest using HRQoL as an abbreviation for Health-related quality of life, rather than writing health-related QoL.

Responses: Thank you for your comment. I had replaced the health-related QOL with HRQoL in the text already.

Comment 2) Background: the last sentence of the first paragraph is not absolutely clear. Could it be rephrased?

Responses: Thank you for your comment. In background section was adjusted;

-The lung function test alone does not provide a measurement of the overall impact of COPD health status, even though it is used for classification disease severity [4]. Effective dialogue between physicians and patients in a consultation can address the impact of COPD on patient’s QoL. The St. George’s respiratory questionnaire (SGRQ) is the standard tool for assessment of QOL in COPD. However, it is lengthy and time consuming [5].

Comment 3) Study assessments and procedures: last sentences has an "and" after call to ref [11], which is probably non intentional.

Responses: Thank you for your comment. I had deleted in already.

Sincerely yours,

[Signature]

Chaicharn Pothirat MD,FCCP.