Peer Review File

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Reviewer A

This research paper assessed the validity and reliability of the Korean PROMIS-29 Profile v2.1 among patients with chronic pulmonary diseases. The paper is well-written and provides useful information about the psychometric properties of this tool to be used in patients with chronic respiratory diseases. However, I have some comments that will improve the quality of the paper.

Thank you for the comments. We have revised the paper in response to these comments.

Comment 1. Line 27: typo error, remove the letter m from the word council

Reply 1: Done.

Comment 2. Line 70-72: unclear sentence, please rewrite

Reply 2: We have revised the sentence more clearly as following

Introduction (page 2, 1st paragraph)

"However, the CAT or mMRC were limited to evaluate other symptoms associated worsening of respiratory symptoms such as fatigue, depression, anxiety, and reduced social functioning. (15-17)"

Comment 3. Line 135: Exploratory and confirmatory factor analyses are used to test structural validity, please adjust your manuscript accordingly

Reply 3: With respect to the reviewer's comment, we revised the sentences like following

Methods (page 5, 4th paragraph)

"An exploratory and confirmatory factor analysis was performed to test structural validity of the K-PROMIS-29 V2.1. For the exploratory factor analysis (EFA), a common factor model with an alpha factor extraction was used.(37) For the confirmatory factor analysis (CFA), we used the maximum likelihood to test whether our factor structure fit the data."

Comment 4. Line 165: change to internal consistency

Reply 4: As the line 165 included the results of EFA and CFA, we revised the subtitle as 'Structural validity.'

Comment 5. Line 175: label as structural validity

Reply 5: We do not see any subtitle or possible working that could be labeled as structural validity. Please let us know if there is any change needs to be made regarding line 175.

Comment 6. Line 226: suggest removing "and" as you only measured internal consistency reliability but no other reliability measures.

Reply 6: With respect to the reviewer's comment, we revised the sentence like following

"The results indicated that the measure's internal consistency was high."

Comment 7. Line 255: be consistent with references, either report before or after the period

Reply 7: Done

Comment 8. Line 257: unclear sentence, please clarify what do you mean of published information needs to be established?

Reply 8: We have revised the sentence more clearly as following:

Discussion (page 10, 3th paragraph)

"Recently, the respiratory disease field has progressed further in assessing patients' daily living activities; however, there is limited research regarding HRQoL among CPD patients.(52)"

Comment 9. Line 272-273: you have not mentioned CPD treatment, suggest rewriting this sentence to Korean patients diagnosed with CPD.

Reply 9: As the reviewer's suggested, we revised the sentence as following: .

Discussion (page 10, 3rd paragraph)

More data are necessary to understand how the K-PROMIS-29 would be summarized and presented to patients diagnosed with CPD."

Comment 10. Line 279-282: I think this information should not be in the conclusion. You may add this to the discussion part in more details

Reply 10: As the reviewer suggested, we now add the sentence to the discussion part. In addition, we revised the conclusion like following:

Discussion (page 10, 3rd paragraph)

"Recently, the respiratory disease field has progressed further in assessing patients' daily living activities; however, there is limited research regarding HRQoL among CPD patients.(52) Clinicians might hesitate to use HRQoL measures such as the PROMIS-29 due to several reasons. They might not use it because they do not have enough resources such as time and personal. (53)In addition, researchers and clinicians would not use the PROMIS-29 because it is not a disease-specific measure and they do not know how to interpret it due to lack of data.(54) While the PROMIS-29 instrument has been tested in other chronic disease patients but is not yet widely used among CPD patients in the clinical settings. More data are necessary to understand how the K-PROMIS-29 would be summarized and presented to patients diagnosed with CPD."

Conclusion (page 11, 2nd paragraph)

"In conclusion, this study provides psychometric evidence for the reliability and construct validity of K-PROMIS-29 V2.1 in a CPD population. Considering that the PROMIS-29 is one of the standard PRO measures recommended for initial outcome assessment, (55) it is encouraged to use the K-PROMIS-29 both for research and clinical care of CPD patients."

Comment 11. Add the psychometric properties of the SF-36, mMRC, & CAT questionnaires

Reply 11: As the reviewer suggested, we now included psychometric properties of the SF-36, mMRC, and CAT questionnaire in the Methods section.

Methods (page 4, 2nd paragraph)

"In this study, the Cronbach alpha of SF-36 was 0.96."

Methods (page 4, 3rd paragraph)

"At the study institution, CAT and mMRC are routinely measured at respiratory outpatient clinics, and we obtained these scores from electronic medical records (EMRs). The CAT comprises the following 8 items: cough, phlegm, chest tightness, breathlessness, limited activities, confidence leaving home, sleeplessness, and energy, defined using contrasting adjectives. Each item was presented as a semantic 6-point (0–5) differential scale, providing a total score ranging from 0 to 40 points.(22) The Cronbach alpha of CAT in this study was 0.91. The mMRC scale is a 5-point scale (0–4) based on dyspnoea severity.(23) The mMRC had a moderate and strong correlation with breathless walking upstairs (r= 0.53) and with home activity limited (r = 0.69) in CAT score, respectively."

Comment 12. Write numbers 1-10 in words

Reply 12: Done

Reviewer B

Overall the introduction needs to be strengthened bit more.

Comment 1. The introduction as written now appears choppy and does not lead well to the purpose of the study. Starting with the first paragraph, explain to the audience how CPD with all the symptom burden can ultimately impact the quality of life.

Reply 1: In response to the reviewer's suggestion, we have revised the introduction as following:

Introduction (page 1, 1st paragraph)

"CPD patients commonly experience multiple respiratory symptoms, including breathlessness, cough, dyspnea, and phlegm.(3,4) In addition, patients experience periodic exacerbations, defined as an acute, sustained worsening of their CPD, resulting in unscheduled clinic or emergency-department visits and hospitalization for treatment.(5,6) There have been many studies supporting that these respiratory symptoms and exacerbations have negative impact on quality of life among CPD patients (7-9) Furthermore, non-

respiratory symptoms such as fatigue and anxiety worsen the CPD patients' quality of life, by limiting physical activities of daily living and causing sleep disturbance at night-time. (7,10-12)"

Comment 2. Then talk about various PROs for assessment of quality of life - disease specific and generic. Also there are other generic measures already existing such as SF-36 and RAND etc. Although the authors use SF-36v2 to examine the validity of the PROMIS tool, they do not talk about it in the introduction. Instead they focus on disease specific measures.

Reply 2: In response to the reviewer's suggestion, we have revised the introduction including SF-36 (SF36-v2 is the updated version of SF-36) and EQ5D as following:

Introduction (page 2, 1st paragraph)

"In fact, generic measurements, such as the EuroQoL-5D (EQ-5D)(18) and the 36-item short-form health survey (SF-36)(19) were frequently used to assess the HRQoL in CPD patients. (20,21) However, the EQ-5D had relatively larger ceiling effect than other HRQoL measures and do not discriminate well severe and mild CPD patients.(22) While the SF-36 is more comprehensive than the EQ-5D,(23) it still does not cover common symptoms for patients with CPD such as fatigue and anxiety. (24) In 2010, the National Institutes of Health in the U.S. developed the Patient-Reported Outcomes Measurement Information System (PROMIS)-29 is a multi-item measure for assessing generic profile health-related quality-of-life (HRQoL).(25) The PROMIS-29 covers frequently reported symptoms such as fatigue and sleep disturbance in CPD patients which are not covered by other generic PRO measures. The instrument has been used to assess HRQoL in patient with chronic disease and older adults with multiple chronic conditions including arthritis, cancer, congestive heart failure, diabetes, osteoporosis, and stroke.(26) Thus, we aim to examine the validity of the Korean PROMIS-29 (K-PROMIS-29) among CPD patients."

Comment 3. line 57: 1s - spell out second

Reply 3: Done

Comment 4. line 77-78: the aim was to examine the validity...

Reply 4: With respect to the reviewer's comment, now we revised the sentence like following:

"Thus, we aim to examine the validity of the Korean PROMIS-29 (K-PROMIS-29) among CPD patients."

Methods:

Study Participants:

Comment 5. line 85: what type of physical conditions were excluded. Was the cognition formally assessed to determine eligibility?

Reply 5:

From September to October 2018, we conducted a cross-sectional survey at respiratory disease outpatient clinics at Samsung Medical Center in Seoul, South Korea to evaluate the HRQoL among patients with respiratory disease. Patients were eligible if they were aged ≥18 years and able to speak and read Korean. Total 304 patients participated in the survey. To validate the K-PROMIS-29 among CPD patients, we included 212 patients with pulmonary tuberculosis, nontuberculous mycobacterial lung disease, bronchiectasis, chronic obstructive pulmonary disease, lung cancer, interstitial lung disease, and asthma in this study. We excluded patients who had history of severe cognitive impairment or Alzheimer diseases according to electronic medical records. To clarify the procedure of study population selection, we now revised the sentences as following:

Methods (page 2, 2nd paragraph)

"From September to October 2018, we conducted a cross-sectional survey at respiratory disease outpatient clinics at Samsung Medical Center in Seoul, South Korea to evaluate the HRQoL among patients with respiratory disease. Of total 304 patients who were aged ≥18 years and able to speak and read Korean participated in the survey. To validate the K-PROMIS-29 among CPD patients, we included 212 patients with pulmonary tuberculosis, nontuberculous mycobacterial lung disease, bronchiectasis, chronic obstructive pulmonary disease, lung cancer, interstitial lung disease, and asthma in this study. We excluded patients who had history of severe cognitive impairment or Alzheimer diseases according to electronic medical records."

Comment 6. the selection criteria does not explain patient diagnoses? How was CPD diagnosed? Which conditions were included? If a person with (for e.g. COPD) also had Alzheimers, was this patient included?

Reply 6: Please see the response to the comment #5.

Comment 7. line 86: trained researchers? Were these the study team or recruited for the purpose of explaining the purpose ? How many researchers? Was it the same person who explained to all patients or different people?

Reply 7: Two researchers who are fully understand our research purpose as our research team and have experiences in patient recruitment independently explained regarding the survey to the patient.

We added this information in the Methods section as following:

Methods (page 3, 1st paragraph)

"Two researchers of the study team explained the survey purpose and procedures to the participants."

Measurement:

Comment 8. The PROMS measure is not very well described and scoring is unclear.

Reply 8: As reviewer requested, we revised the sentence to more clearly.

Methods (page 3, 2nd paragraph)

"Domain scores were obtained by summing the item scores for each domain. The range of each domain was 4 to 20. Higher scores represent better physical function, ability to participate in social roles and activities, and more severe levels of anxiety, depression, fatigue, sleep disturbance, pain interference and pain intensity. In addition, we also converted the raw score into t-scores standardized for the general US population [mean (SD) 50 (10)] using a T-score metric via Assessment Center (https://www.assessmentcenter.net; Northwestern University, Evanston, Illinois, USA).(25,29)"

Comment 9. Line 119: Why were mMRC and CAT scores obtained from EMR data? Why were these not administered to the patient? Since health status changes over time,

it is likely that using older data on symptoms might not align with their present health status. It is also unclear how old was this data? The scores on these measures - were these from last month or last year?

Reply 9: Please see the response to the comment #11 of the Reviewer 1.

Comment 10. It is unclear which measure was used as reference for discriminant validity?

Reply 10: We hypothesized that discriminant validity would be evident if the correlation between a subscale and its corresponding component score was higher than the correlation between the subscale and the other component score. We expected associations between similar domains in K-PROMIS-29 V2.1 and SF-36v2 as convergent validity (physical function in K-PROMIS-29 V2.1 and physical functioning in SF-36v2, ability to participate in social roles and activities domain in K-PROMIS-29 V2.1 and role-physical, role-emotional and social functioning in SF-36v2, anxiety and depression in K-PROMIS-29 V2.1 and mental health in SF-36v2, and pain interfere in K-PROMIS-29V2.1 and bodily pain in SF-36v2), and relatively low associations between other domains as discriminant validity. We revised the Methods section to more clearly.

Methods (page 5, 5th paragraph)

"To examine convergent and discriminant validity, hypotheses on the direction and magnitude of Pearson's correlations between the K-PROMIS-29 V2.1 and SF-36v2 were formulated a priori.(33) We expected high correlations between conceptually similar domains in K-PROMIS-29 V2.1 and SF-36v2 as convergent validity (marked in grey in Table 4), and low correlations between conceptually different domains as discriminant validity. Moderate (0.5 <|r| <0.7) or large correlations (|r| ≥0.7) were considered to indicate convergent validity.(40)"

Table 4R. Pearson's correlation coefficients comparing the K-PROMIS-29 with the SF-36v2

SF-36v2	K-PROMIS-29v2						
	Physical function	**Ability to participate in social roles and activities**	**Anxiety**	**Depression**	**Pain interference**	**Fatigue**	**Sleep disturbance**
Physical functioning	**0.70***	0.59*	-0.42*	-0.41*	-0.52*	-0.59*	-0.27*
Role-physical	**0.66***	**0.64***	-0.44*	-0.49*	-0.59*	-0.59*	-0.32*

Role-emotional	0.59*	**0.64***	-0.50*	-0.51*	-0.58*	-0.59*	-0.29*
Social functioning	**0.61***	**0.65***	-0.54*	-0.53*	**-0.63***	**-0.67***	-0.39*
Mental health	0.48*	0.57*	**-0.62***	**-0.68***	-0.47*	**-0.64***	-0.33*
Bodily pain	0.40*	0.50*	-0.37*	-0.38*	**-0.69***	-0.48*	-0.38*
Vitality	0.60*	**0.64***	-0.55*	-0.55*	**-0.61***	**-0.75***	-0.45*
General health	0.45*	0.52*	-0.46*	-0.50*	-0.51*	**-0.61***	-0.41*

In this data set, role-physical (n=1) and role-emotional (n=1) had missing data.
The expected associated domain between similar domains in K-PROMIS-29 V2.1 and SF-36v2 was highlighted in grey.

Comment 11. Discussion: Focusses on feasibility which was not the purpose of the study. Discussion needs more focus on the findings of the study and explanation of the findings in relation to other published research.

Reply 11: With respect to the reviewer's comment, we included sentence regarding the findings of the study and explanation of the findings in relation to other published research as following:

Discussion (page 10, 3rd paragraph)

"The instrument has been validated in patient with cancer, (44) kidney disease (45)and Chronic Musculoskeletal Pain.(46)In this study, we also found the Cronbach's α coefficients for all subdomains fell within the range of acceptable internal consistency.(47)"

Discussion (page 10, 3rd paragraph)

"Recently, the respiratory disease field has progressed further in assessing patients' daily living activities; however, there is limited research regarding HRQoL among CPD patients.(52) Clinicians might hesitate to use HRQoL measures such as the PROMIS-29 due to several reasons. They might not use it because they do not have enough resources such as time and personal. (53)In addition, researchers and clinicians would not use the PROMIS-29 because it is not a disease-specific measure and they do not know how to interpret it due to lack of data.(54) While the PROMIS-29 instrument has been tested in other chronic disease patients but is not yet widely used among CPD patients in the clinical settings. More data are necessary to understand how the K-PROMIS-29 would be summarized and presented to patients diagnosed with CPD."

Conclusion (page 11, 2nd paragraph)

"In conclusion, this study provides psychometric evidence for the reliability and construct validity of K-PROMIS-29 V2.1 in a CPD population. Considering that the PROMIS-29 is one

of the standard PRO measures recommended for initial outcome assessment, (55) it is encouraged to use the K-PROMIS-29 both for research and clinical care of CPD patients."

Comment 12. Tables are well constructed.

Reply 12: Thank you.