Health-related Quality of Life in Patients with Pulmonary Infection with Nontuberculous Mycobacterium

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Abstract

Background and objective: The health-related quality of life (HRQoL) in patients with pulmonary infection with nontuberculous mycobacterium (pNTM) has not yet been quantified. To validate the COPD Assessment Test (CAT) and St. George's Respiratory Questionnaire (SGRQ) in quantifying the HRQoL of patients with pNTM, we evaluated the reliability and validity of these questionnaires.

Methods: We performed a cross-sectional study in a group of fifty-two patients with pNTM. All the subjects completed the questionnaires of CAT, SGRQ, Short Form-36 Health Survey (SF-36) as well as pulmonary function test (PFT). The test-retest was performed and the Cronbach α was calculated to assess the reliability. The correlations of the CAT and SGRQ with SF-36 and PFT were performed correspondingly to assess the validity.

Results: The mean age of the patients was 67 years old and 96 % were female (50/52). The test-retest showed good correlation of day 1 test with day 5 retest in both individual and total scores of CAT and SGRQ. Meanwhile, the Cronbach α (0.77-0.92) indicated a satisfied internal consistency. Moreover, all the scores were correlated moderately/strongly with the SF-36 physical component summary score.

Conclusions: The SGRQ and CAT showed significant validity in assessing the HRQoL

in patients with pNTM.

Keywords: pulmonary nontuberculous mycobacterial infection, health-related quality of life, St. George’s Respiratory Questionnaire, COPD Assessment Test.

Introduction

The symptoms of pulmonary nontuberculous mycobacterium infection (pNTM) are variable and nonspecific, such as cough, sputum, dyspnea, fever, hemoptysis, and weight loss.[1] Some of the patients with pNTM have prominent symptoms, however, others have few symptoms or are asymptomatic. The treatment of pNTM comprises of prolonged multi-drug therapy, which is often recurrent after treatment and associated with significant toxicities.[1,2] As a result, it is uncertain as to when the treatment should be started, based on an assessment of the patients' status, according to their clinical information, such as the health-related quality of life (HRQoL) including symptoms, chest radiograph, computed tomography (CT) findings, and sputum culture results. However, the application of objective tests to evaluate the HRQoL in patients with pNTM has only seldom been reported.[3,4]

It is important to evaluate the HRQoL in patients with other chronic pulmonary diseases.[5] The HRQoL tests have been applied to evaluate the quality of life in patients with several chronic respiratory diseases, including chronic obstructive pulmonary disease (COPD), asthma, bronchiectasis, and so on.[6-12] It is important and compulsory to assess the HRQoL of patients with pNTM before starting the treatment. However, there are no objective tests to assess the HRQoL of patients with pNTM at present.

Questionnaire of COPD Assessment test (CAT) was specifically designed to evaluate the quality of life in patients with COPD.[13] The CAT is short and simple, and can easily be applied to the patients without requiring copyright holder's permission. The CAT was significantly correlated with all domains of the Chronic Respiratory Questionnaire in patients with chronic respiratory diseases such as interstitial lung disease, asthma, and bronchiectasis, as well as COPD.[14,15] However, the CAT was not validated for assessment of HRQoL in patients with pNTM. In addition, despite that the St. George's Respiratory Questionnaire (SGRQ) was specifically designed to evaluate the quality of life in patients with asthma and COPD,[16] it was previously reported to be validated in assessment of quality of life in patients with other pulmonary diseases such as bronchiectasis and chronic pulmonary aspergillosis through comparison of the SGRQ with Short Form-36 Health Survey (SF-36) that was a questionnaire in the assessment of quality of life for general diseases.[8,17] There are evaluation of the correlations between the SGRQ with pulmonary function test (PFT) and CT shadows in patients of pNTM,[3,4] but study to validate the SGRQ in evaluation of HRQoL in patients with pNTM has not yet reported.

In order to verify the validity of SGRQ and CAT in assessment of HRQoL in patients with pNTM, we evaluated the HRQoL of patients with pNTM using the SGRQ and

CAT and compared the results with those obtained through the SF-36. Pulmonary infection with mycobacterium avium-intracellulare leads to air trapping distal to the small airways.[18] Therefore, we also analyzed the association of HRQoL with the PFT and the 6 minutes of walking distance (6MWD) in patients with pNTM.

MATERIALS AND METHODS

Ethics statement

The current study was approved by the Ethics Committee of Shinshu University School of Medicine (Matsumoto, Japan). The protocol was performed in accordance with the principals outlined in the Declaration of Helsinki of the World Medical Association and was approved by the Ethics Committee of Shinshu University School of Medicine. Informed consent was obtained from each subject after providing them a full explanation of the study.

Patients

This research is a cross-sectional study, and there were few reports about the assessment of HRQoL in patients with pNTM. The sample size was referred to a previous report in

which the number of patients was 51.[3]

The patients were consecutively recruited in our department. All patients visited Shinshu University Hospital due to cough and/or sputum and abnormal findings on their chest radiographs and/or CT scans, such as multiple small nodules, bronchiectasis, consolidation, and/or cavities suggesting a pNTM. The diagnosis of pNTM was based on the criteria established by the American Thoracic Society/Infectious Disease of America.[1] The sputum was cultured on at least two separate occasions. When the patients had no sputum and/or the sputum cultures were negative, the samples obtained from pulmonary lesions through a sterilized fiberoptic bronchoscope under chest radiography were used instead. All of the patients were free from other distinct lung diseases and HIV infection. The male patients were predominantly less than females in pNTM in Japan, so only two male patients were recruited in this study.

Health-related quality of life (HRQoL)

The HRQoL of the patients was assessed using the Japanese version of questionnaires of SGRQ (version2), CAT, and SF-36. The SGRQ consists of 76 items and provides three domain scores (symptoms, activity, and impact) with a total score ranging from 0 (optimal) to 100 points (worst).[16,19] The CAT consists of eight items, including cough,

phlegm, chest tightness, breathlessness going up hills / stairs, activity limitation at home, confidence leaving home, sleep, and energy, ranging from 0 (best possible health) to 40 (worst possible health) points.[13,20] The SF-36 is a questionnaire for general health status and consists of 36 items, which provides scores for eight health domains (Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health), a psychometrically-based physical component summary (PCS), and a mental component summary (MCS) with a normal adjustment score of 50.[21,22] This SF-36 tool for HRQoL has been used to evaluate the general health status of patients with chronic respiratory diseases.[8,17,23-25] These tests were done by different instructors.

At day 1, patients with pNTM were performed PFT, 6MWD and each of the three questionnaires (SGRQ, CAT, and SF-36). The physician was near the patients when they were given the questionnaires and explained the questionnaire if any questions. The test-retest model was used to evaluate the reliability of the instruments over time. The CAT, SGRQ, and SF-36 were completed twice over five days from the first time of examinations at home. The patients brought their questionnaires on their next hospital visit.

Pulmonary function test

Each parameter in Spirometry was measured in accordance with the American Thoracic Society protocol and Japanese Respiratory Society.[26-29] The normal range was defined as the measured values within 80% -120% of the predicted one in PFT.[30]

Statistical analysis

The data of continuous variables are presented as the mean± standard deviation (SD). The data were entered twice into a database (Excel; Microsoft; Richmond, WA) and discrepancies were queried and corrected. The answers on the questionnaires were scored using the scoring calculator (Excel-based) provided with the instrument. Total and component scores were obtained. Each participant's score was matched to the results of their PFT and that of their 6MWD through a sequential identifying number. The data were analyzed using a statistical software package (SPSS, version 12 for Windows; SPSS Inc; Chicago IL). Correlations were determined using the Spearman rank correlation coefficient. There was a weak correlation if the correlation coefficient was less than 0.4, a moderate correlation if the correlation coefficient was 0.4-0.6, and a strong correlation when the correlation coefficient was over 0.6. The Cronbach α was calculated to assess the consistency in SGRQ and CAT. Statistical significance was

considered to exist when $P < 0.05$.

Results

Characteristics and pulmonary function test of patients

The characteristics and pulmonary function values of patients are shown in Table 1. The patients tended to be middle-aged to older women, including 50 women and 2 men with average age of 66.8±8.9 years. The average body mass index (BMI) was 18.9±2.1. All patients showed shadows on both lungs in chest CT imagines. Regarding the types of mycobacteria in the 52 patients, 38 patients was *M.avium*, 7 was *M.intracellulare*, 1 was *M.kansasii*, 1 was *M.abscessus*, 3 was identified two types mycobacteria (*M.avium* and *M.intracellulare*) and 2 was unidentified. The average values of %VC, $\%FEV_1$, %RV, %TLC were all above 80%, while the mean value of %DLco was slightly lower than 80%. The mean value of the 6MWD was 535.4±90.2 meters.

The HRQoL of patients evaluated by CAT, SGRQ, and SF-36

The results of the HRQoL of patients are shown in Table 2. All patients completed the CAT and SGRQ at day 1 test and day 5 retest. The mean CAT total score was 10.2 and the CAT score at day 1 was strongly correlated with the CAT score at day 5 (r=0.85) in

the test-retest with satisfied internal consistency (Cronbach α= 0.88). Questions of cough, sputum, and effort showed relatively high scores among the eight items of CAT in the present study group. The total score and average score of each of the three SGRQ domains (symptom, activity, and impact) at day 1 were 21.6, 32.8, 25.2, and 16.0, respectively. These scores were higher in the present pNTM than healthy subjects with no history respiratory disease in SGRQ manual Ver2.3. In addition, the scores of SGRQ (total, symptom, activity, and impact) at day 1 were strongly correlated with those of the SGRQ at day 5 (r= 0.82-0.91) with satisfied internal consistency (Cronbach α= 0.77-0.92). The CAT score showed a close correlation with SGRQ score (r= 0.76) (Figure 1). The mean scores of each of SF-36 domain (physical functioning, role physical, general health, vitality, social functioning, role emotional, mental health) except domain of bodily pain was below 50 points. The mean PCS score was below 50 points, while there was no decline in MCS score.

Correlations of the CAT and SGRQ with SF-36 and the pulmonary function test

The correlations of the CAT and SGRQ with SF-36 and PFT are shown in Table 3 and Figure 2. Both the total CAT and SGRQ scores were strongly/moderately in negative correlations with the PCS and MCS of the SF-36. Each score of the SGRQ domains

(symptom, activity, and impact) were moderately/weakly in negative correlations with PCS and MCS of SF-36.

Regarding the PFT, the %DLco showed a moderately negative correlation with the scores of SGRQ and CAT, and 6MWD showed a weakly negative correlation with the scores of SGRQ and CAT. The %VC, $\%FEV_1$, %FRC, and %RV did not show any correlations with the CAT scores. Additionally, the $\%FEV_1$ and %RV did not show correlations with the SGRQ scores.

Discussion

In the present study, we validated the utility of the SGRQ and CAT in an evaluation of the general HRQoL of patients with pNTM. All patients took a test-retest, completing the SGRQ and CAT two times with an interval period of five days, which assessed the stability of the SGRQ and CAT. The SGRQ and CAT showed a good correlation between day 1 test and day 5 retest in the patients with pNTM. In addition, the Cronbach α was calculated to assess the consistency, which indicated that the SGRQ and CAT showed a satisfactory internal consistency. Moreover, to validate the SGRQ and CAT, the validity and reliability of these questionnaires were assessed. And to assess the validity of the SGRQ and CAT, the correlations of the SGRQ/CAT with

SF-36 as a general HRQoL questionnaire were investigated. Taking all together, the stability, consistency and validity of these questionnaires suggested the reliability of the SGRQ and CAT in the evaluation of general HRQoL for patients with pNTM.

Each score on the questionnaire indicated that the patients with pNTM had more significant impairments than those of a healthy population.[22,31] The SF-36 has been used to assess the HRQoL of patients with various diseases including pulmonary diseases. Although there were a few reports about the evaluation of HRQoL in pNTM by SF-36, Mehta et al. reported that patients with pNTM disease had significantly impaired HRQoL, with similarities associated with other common chronic diseases, such as ischemic heart disease, diabetes, arthritis, and chronic lung disease.[3] In agreement, the scores of each of the SF-36 domains suggested that patients with pNTM were significantly impaired when compared to a healthy population in the present study. The only bodily pain score reported was a mean score of almost fifty. We considered that cough, sputum, and fever frequently occurred as a symptom of pNTM, but pain was very rare. Regarding the PCS and MCS in our study, the PCS was less than the MCS, as already reported.[3]

Regarding the SGRQ, the symptom, activity, impact, and total scores were worse in the pNTM patients than in the healthy population.[3,31] However, each score was relatively

low when compared to previously reported studies,[3] indicating a relatively high QoL of patients with pNTM in present study; this is probably due to their relatively good results from their PFT.[3] In addition, the small proportion of pNTM with current treatment indicated fewer patients with severe condition in our study. The scores of the SGRQ symptom, activity, impact, and total were significantly negatively correlated with the scores of the SF-36 PCS and MCS, demonstrating that the SGRQ might be reliable in the utility to assess the HRQoL in patients with pNTM.

The questionnaire of the CAT was designed to assess the QoL of patients with COPD, and specifically was used to determine the staging in Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification.[32] Up to now, no investigation has yet been reported about the validation of the CAT in patients with pNTM. According to the GOLD classification, by which the severe class was defined as, the mean CAT score was more than 10,[32] the patients with pNTM with the mean CAT scores of 10.2±7.3 in our study were classified into the severe class with some impaired symptoms in daily life. In our results, the mean CAT score showed a strong negative correlation with the SF-36 PCS, and showed a moderate negative correlation with the SF-36 MCS. PCS has a better correlation than MCS with the mean CAT, because the CAT consisted of the majority of symptom items. As validation for the use of the CAT in COPD, Jones et al.

reported that the CAT showed a significant correlation with the SGRQ (r=0.80).[13] In the present study, CAT showed a good correlation with SGRQ (r= 0.76) (Figure 1). Because the CAT was a short and simple instrument with no necessary permission needed for its usage, we proposed that using the CAT as the protocol, as the HRQoL tool, for the assessment of QoL in patients with pNTM.

Regarding the relationship of the HRQoL with the PFT and with the 6MWD test, Jones et al. reported that the SGRQ total scores were poorly correlated with $\%FEV_1$ and RV/TLC and the physiological index, such as PFT, should be measured independently in patients with COPD.[33] Similarly, there was a dissociation between the SGRQ total scores and the PFT in patients with pNTM in this study.

Mehta et al. reported that the SF-36 PCS correlated with %FVC, $\%FEV_1$, and %DLCO, and the SGRQ total score correlated with %FVC and $\%FEV_1$.[3] In our study, the SGRQ scores showed a significantly negative correlation with the $\%DL_{CO}$, but there were no or weak correlations with %VC, $\%FEV_1$, %FRC, %RV, and 6MWD. One of the reasons might be that the patients in our study were generally in better condition in their PFT when compared to those patients with pNTM in other reference studies.[3] In the present study, patients with pNTM showed a value of $\%DL_{CO}$ lower than the normal range, however, the values of %VC, $\%FEV_1$, %FRC, and %RV were all within normal ranges.

It is possible that the worsening of SGRQ scores might provide an early indication of the impairment of pulmonary function in patients with pNTM. Therefore, the HRQoL, as measured by the CAT and SGRQ, should be evaluated independent of the physiological index.

Conclusion

The SGRQ and CAT are significantly valid for the assessment of HRQoL in patients with pNTM, independent of physiological indices such as the PFT and 6MWD. Assessing the HRQoL in patients with pNTM objectively using the SGRQ and CAT may guide appropriate therapeutic strategies in the treatment for pNTM.

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Author contributions

Mineyuki Hama and Atsuhito Usihiki had the final responsibility of ensuring the integrity of the data and making the decision to submit. Makoto Kosaka, Yoshitaka Yamazaki, Masanori Yasuo, Hiroshi Yamamoto, and Masayuki Hanaoka contributed to collecting data and all authors agreed with the contents of the published version.

Conflict of interest

The authors declare that there are no conflict of interest.

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Figure Legends：

Figure 1. Correlation of the CAT total and SGRQ total score at day 1.

The CAT at day 1 closely correlated with the SGRQ total at day1(r= 0.76).

Figure 2. (a) Correlation of the CAT total score with the SF-36 PCS.

There was a strong negative correlation between the CAT and the PCS of SF-36(r=-0.63) .

Figure 2. (b) Correlation of the CAT total score with the SF-36 MCS.

There was a moderate negative correlation between the CAT and the MCS of SF-36(r=-0.46).

Table 1. Clinical characteristics and pulmonary function test results of the patients

	Patients	Range
Sex ratio, M/F	2 / 50	
Age, year	66.8 ± 8.9	35-82
body height, cm	155.0 ± 7.0	129.4-170.0
body weight, kg	45.5 ± 7.1	30.6-65.0
BMI, kg/㎡	18.9 ± 2.1	16.3-22.4
Pulmonary function test		
VC predicted,%	92.1 ± 18.6	35.0-129.0
FEV_1 predicted,%	92.6 ± 21.8	44.6-151.7
FRC predicted,%	121.2 ± 22.2	59.1-172.5
RV predicted,%	109.3 ± 20.4	69.7-168.2
TLC predicted,%	107.2 ± 16.6	53.2-135.4
DLco predicted,%	75.9 ± 17.8	30.2-116.4
6MWD, m	535.4 ± 90.2	329-725

Data are presented as the mean ± standard deviation (SD) except sex ratio.

Abbreviations: BMI = body mass index; VC = vital capacity; FEV_1 = forced expiratory

volume in 1 second; FRC = functional residual capacity; RV = residual volume; TLC = total lung capacity; DLco = diffusion capacity for carbon monoxide; 6MWD = six-minute walk distance.

Table 2. The HRQoL of patients with pulmonary nontuberculous mycobacterium as evaluated by the CAT, SGRQ, and SF-36

Measures	Mean Score ± SD (At Day1)	Mean Score ± SD (At Day5)	r	Internal Consistency Reliability
CAT				
Total	10.2±7.3	10.9±7.5	0.85	0.879
SGRQ				
Symptom	32.8±18.9	30.6±20.2	0.84	0.828
Activity	25.2±18.6	27.5±20.0	0.82	0.918
Impact	16.0±15.1	16.7±15.0	0.86	0.773
Total	21.6±17.1	22.2±18.1	0.91	0.911
SF-36				
Physical functioning	45.0±12.0			
Role physical	42.4±15.0			
Bodily pain	50.1±10.2			
General health	43.3±9.1			

Vitality	49.3±9.0
Social functioning	46.9±11.9
Role emotional	44.6±13.1
Mental health	48.8±8.5
PCS	42.6±14.3
MCS	50.0±7.1

The data are presented as the number of patients of the mean± standard deviation (SD). CAT = COPD assessment test; SGRQ = St. George's Respiratory Questionnaire; SF-36 = Short Form-36 Health Survey; PCS = physical component summary; MCS = mental component summary.

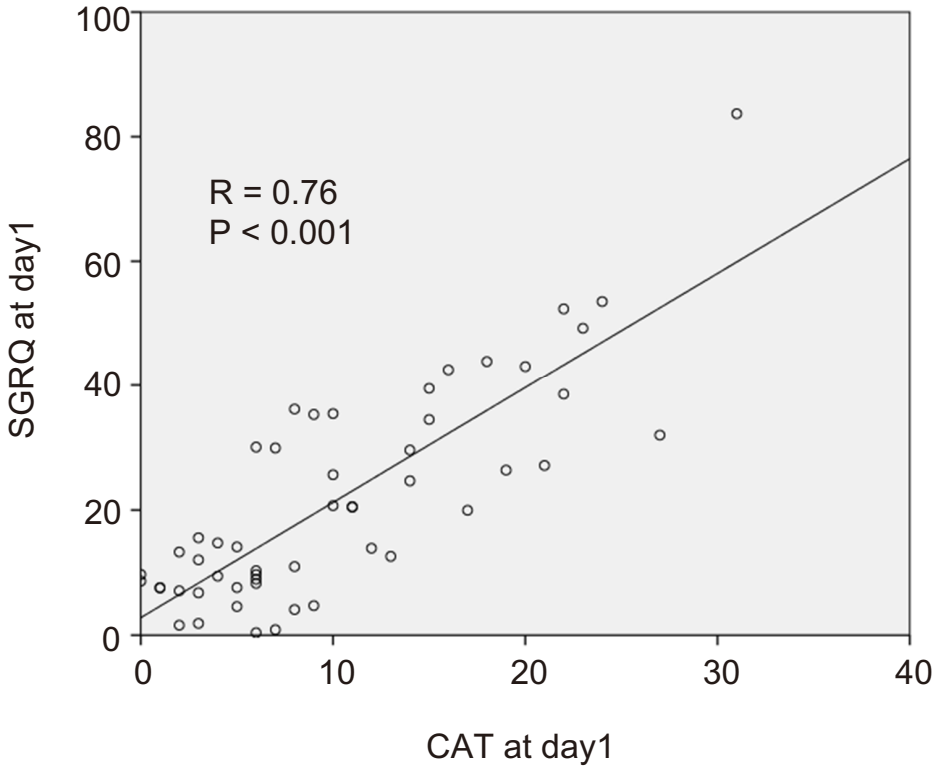
Table 3. Correlations of the CAT total score and each domain score of the SGRQ (total, symptom, activity, and impact) with the SF-36 and the pulmonary function test

Measure	r	p
CAT		
CAT-PCS	-0.63	<0.001
CAT-MCS	-0.46	<0.001
CAT-%VC	-0.12	NS (0.42)
CAT-%FEV1	-0.11	NS (0.45)
CAT-%FRC	-0.27	NS (0.053)
CAT-%RV	-0.15	NS (0.29)
CAT-%DLco	-0.41	<0.001
CAT-6MWD	-0.32	<0.05
SGRQ		
SGRQ (total)-PCS	-0.57	<0.001
SGRQ (total)-MCS	-0.42	<0.01
SGRQ (symptom)-PCS	-0.54	<0.001

SGRQ (symptom)-MCS	-0.39	<0.01
SGRQ (activity)-PCS	-0.53	<0.001
SGRQ (activity)-MCS	-0.30	<0.05
SGRQ (impact)-PCS	-0.49	<0.001
SGRQ (impact)-MCS	-0.46	<0.001
SGRQ (total)-%VC	-0.30	<0.05
SGRQ (total)-%FEV1	-0.17	NS (0.24)
SGRQ (total)-%FRC	-0.29	<0.05
SGRQ (total)-%RV	-0.15	NS (0.28)
SGRQ (total)-%DLco	-0.54	<0.001
SGRQ (total)-6MWD	-0.30	<0.05

CAT = COPD assessment test; SGRQ = St. George's Respiratory Questionnaire; SF-36 = Short Form-36 Health Survey; PCS = physical component summary; MCS = mental component summary. %VC = percentage predicted vital capacity; $\%FEV_1$ = percentage predicted forced expiratory volume in 1 second; %FRC = percentage predicted functional residual capacity; %RV = percentage predicted residual volume; %TLC = percentage predicted total lung capacity; %DLco = percentage predicted diffusion

capacity for carbon monoxide; 6MWD = 6 minutes walking distance.


R = 0.76
P < 0.001
SGRQ at day1
CAT at day1
0
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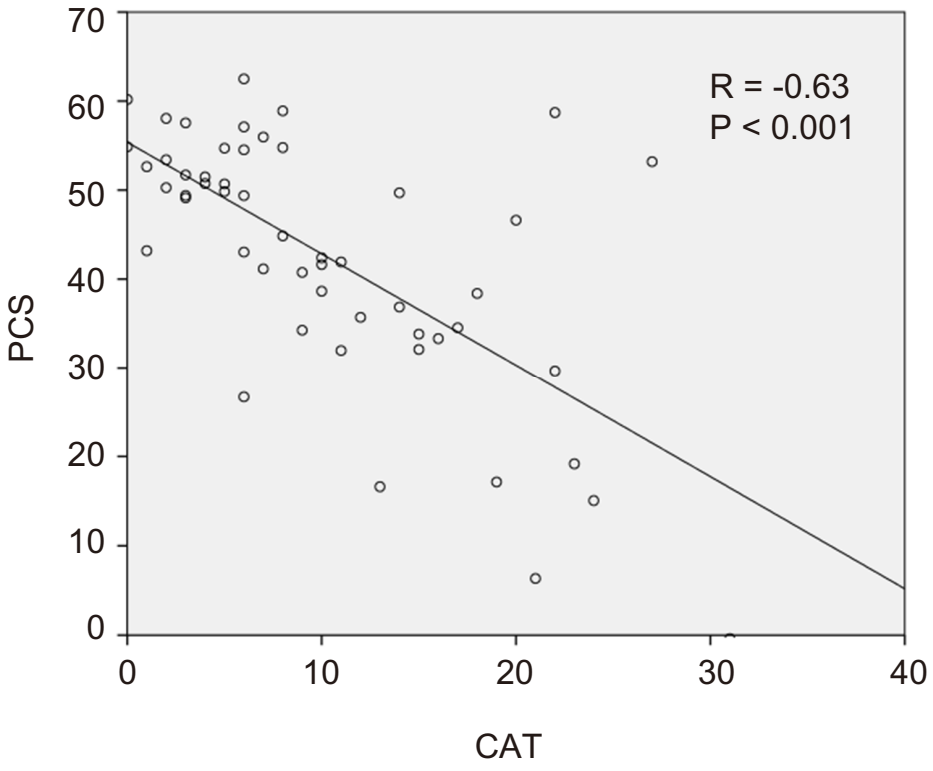
R = -0.63
P < 0.001
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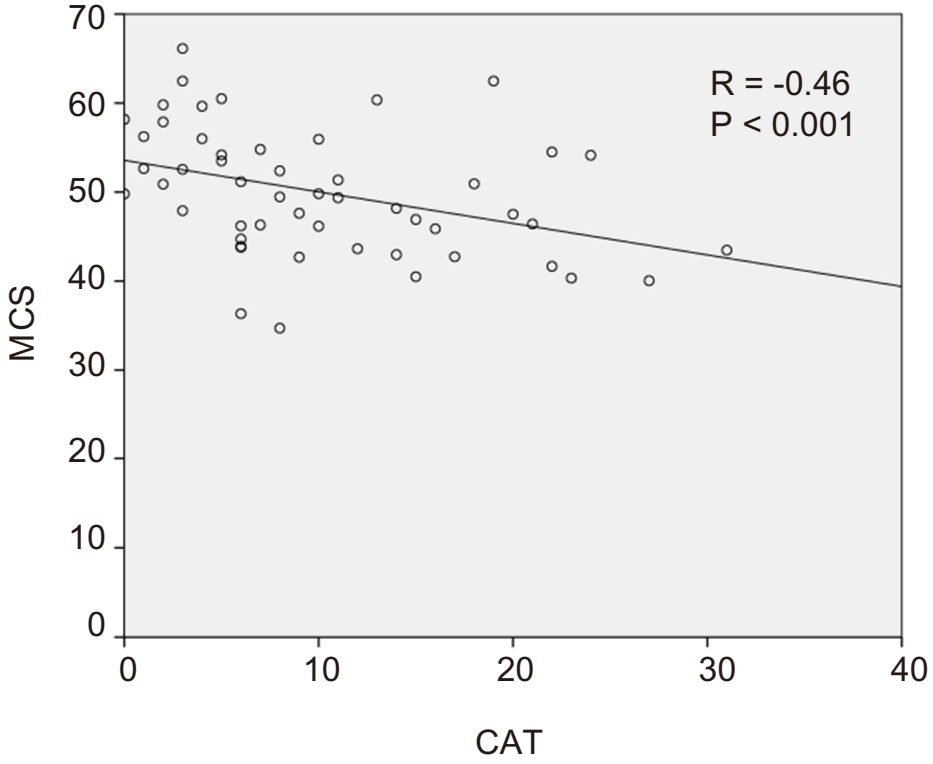
30
40


R = -0.46
P < 0.001
MCS
CAT
70
60
50
40
30
20
10
0
0
10
20
30
40