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Validation of Serbian version of chronic obstructive pulmonary disease assessment test

Validacija sprske verzije upitnika za procenu hronične opstruktivne bolesti pluća

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Abstract

Background/Aim. The Chronic obstructive pulmonary disease (COPD) Assessment Test (CAT) is a simple and reliable tool designed to measure overall COPD related health status and complement physician assessment in routine clinical practice. Objective of this study was to evaluate the validity of the Serbian version of CAT. **Methods.** Study included 140 outpatients in the stable COPD, recruited from two centres: Clinic for Pulmonology, Clinical Center of Serbia, Belgrade, and Institute for Pulmonary Diseases of Vojvodina, Sremska Kamenica. All patients completed pulmonary function testing – spirometry, the CAT and the modified Medical Research Council (mMRC) dyspnea scale at baseline visit. The CAT test-retest reliability was tested in 20 patients by the same investigator (physician). **Results.** We demonstrated that Serbian version of CAT had high internal consistency with Cronbach's alpha 0.88. Test-retest analysis showed good correlation between CAT scores in two time points (Spearman's $\varrho = 0.681$, $p < 0.01$). In our study the CAT correlated moderately to mMRC scale ($\varrho = +0.57$), weakly to FEV_1 (ϱ -0.214), was positively related to number of exacerbations, but did not showed exact regularity with change in the Global Initiative for Chronic Obstructive lung disease (GOLD) stage. **Conclusion.** The Serbian version of CAT is a reliable, simple and easy-to-use tool that can be used in everyday clinical practice to assess the health status of COPD patients in Serbia.

Key words:
pulmonary disease, chronic obstructive; surveys and questionnaires; serbia; comorbidity; forced expiratory volume.

Apstrakt

Uvod/Cilj. Upitnik za procenu hronične opstruktivne bolesti pluća (HOBP) (engl. *COPD Assessment Test* - CAT) je jednostavan i pouzdan test namenjen za merenje ukupnog zdravstvenog stanja bolesnika sa HOBP i koristan je za upotrebu u svakodnevnoj kliničkoj praksi. Cilj ovog istraživanja bio je da se proceni validnost i opravdanost primene srpske verzije CAT. **Metode.** U studiji je učestvovalo 140 bolesnika u stabilnom stanju HOBP, ispitivanih u ambulantnim uslovima na Klinici za pulmologiju, Kliničkog centra Srbije u Beogradu i Institutu za plućne bolesti Vojvodine u Sremskoj Kamenici. Tokom prvog pregleda bolesnicima je učinjeno ispitivanje plućne funkcije (spirometrija), popunili

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su CAT upitnik i mMMR (*modified Medical Research Council*) skalu za procenu stepena dispneje. Pouzdanost CAT test-retesta je ispitivana kod 20 bolesnika od strane istog istraživača. **Rezultati.** Pokazali smo da srpska verzija CAT ima visoku internu konzistentnost sa Cronbach-ovim alfa 0.88. Test-retest analiza pokazala je dobru korelaciju između CAT rezultata u dve vremenske tačke (Spearmanov r = 0,681; $p < 0,01$). CAT je umereno korelirao sa mMRC skalom (r = + 0,57), blago sa forsiranim ekspiratornim volumenom u prvoj sekundi (FEV_1), (r -0,214), uz pozitivnu korelaciju sa ukupnim brojem pogoršanja HOBP, ali bez jasne regularnosti sa promenom GOLD (*Global Initiative for Chronic Obstructive Lung Disease*) stadijuma. **Zaključak.** Srpska verzija CAT je pokazala visoku internu konzistentnost i test-retest pouzdanost. Ona predstavlja pouzdano, jednostavno i lako sredstvo za upotrebu koje se može koristiti u svakodnevnoj kliničkoj praksi za procenu zdravstvenog stanja kod bolesnika sa HOBP u Srbiji.

Ključne reči:
pluća, opstruktivne bolesti; hronične; ankete i upitnici; srbija; komorbiditet; ekspiratorni volumen, forsirani.

Introduction

The Global initiative for Chronic Obstructive Lung Disease (GOLD) strategy document defined chronic obstructive pulmonary disease (COPD) as a preventable and treatable disease, with persistent respiratory symptoms and airflow limitation [1]. Smoking is the main risk factor for disease development along with environmental exposures to biomass fuels and air pollution. Also, individual predisposing factors such as genetic abnormalities, abnormal lung development, and accelerated aging contribute to COPD developing. A course of the disease is often progressive and associated with significant comorbidities which increase its morbidity and mortality.

COPD is one of the most common diseases with a global prevalence of 11.7% [2]. Prevalence of chronic bronchitis symptoms in Belgrade, Serbia was 21.6% [3]. Also, in the other study COPD diagnosis, confirmed by the pulmonologist, was in 21.9% of the patients and newly diagnosed COPD in 10.9% of the patients [4].

COPD is one of the fastest growing causes of death and it is expected to be the 3rd cause of mortality by 2020 worldwide [1]. The disease may cause disability and the quality of life is one of the treatment goals. Health status assessment in COPD patients is a routine in clinical research studies with comprehensive but time-consuming
tools such as the St. George's Respiratory Questionnaire (SGRQ), the Chronic Respiratory Disease Questionnaire (CRQ) and the COPD Clinical Questionnaire (CCQ) [5–7].

The COPD Assessment Test (CAT) is a simple and reliable tool designed to measure overall COPD-related health status and complement physician assessment in routine clinical practice [8]. It is a short, self-administered, eight-item questionnaire that includes symptoms, limitation of daily activity, sleep quality and energy, providing a single score. It is easy to complete by the patient and interpret by the clinician. The CAT was developed and validated internationally, in the Europe and United States, and has been translated into many languages worldwide [9].

The GOLD recognized the importance of the CAT in the multidimensional system of assessment of the disease severity and selection of pharmacological treatment, as well as monitoring of the disease.

The aim of this cross-sectional study was to evaluate the validity of the Serbian version of the CAT.

Methods

The study was conducted in accordance with the Good Clinical Practice as outlined in the Declaration of Helsinki 2000. All necessary approvals for the trial were obtained from respective institutional review and ethical boards.

Study population and design

The study was independently conducted, and 140 patients were recruited from two Serbian centres: the Clinic for Pulmonology, Clinical Center of Serbia, Belgrade (98 subjects) and the Institute for Pulmonary Diseases of Vojvodina, Sremska Kamenica (42 subjects) from May 2017 to January 2018.

They were outpatients in the stable stage of COPD, older than 40 years of age, smokers or ex-smokers. COPD was diagnosed according to the GOLD criteria [1], not earlier than 6 months prior to the study. Inclusion criteria were COPD stable stage and written informed consent. Exclusion criteria were: active respiratory disorder other than COPD, immunosuppression, or subjects unable to complete the questionnaires. Stable COPD is defined as no change in respiratory state in duration of 4 weeks that requires no change in therapy, or systemic steroids and/or antibiotics use. Patient characteristics included demographic information, smoking, COPD and exacerbations history, therapy and comorbidities (cardiovascular diseases – heart failure, arterial hypertension, ischemic heart disease, arrhythmia, peripheral artery diseases, osteoporosis, depression, diabetes, and gastroesophageal reflux). At the baseline visit, the patient's breathlessness was assessed using the Modified Medical Research Council (mMRC) dyspnea scale, and spirometry test was performed according to the American Thoracic Society/European Respiratory Society (ATS/ERS) spirometry guidelines [10]. Patients are further classified according to the airflow limitation severity based on post-bronchodilator forced expiratory volume in the first second (FEV_1) in patients with FEV_1/forced volume vital capacity (FVC) < 0.70 to the GOLD stages: mild – GOLD 1 ($FEV_1 \geq 80\%$), moderate

– GOLD 2 (FEV_1 50–79%), severe –GOLD 3 (FEV_1 30–49%), and very severe –GOLD 4 (FEV1 < 30%). The CAT was administered to all the patients at the baseline visit by the same investigator (physician). The CAT was again administered to twenty patients by the same investigator, at the second visit, 14 days after the first one.

Questionnaire

The CAT is a disease-specific questionnaire assessing health status in individuals with COPD. The CAT and CAT logo is a trade mark of GlaxoSmithKline group of companies. The CAT can be freely used. For this study we used already available Serbian translation of CAT written in consistent and understandable language, so there was no need for back-translation analysis. The CAT consists of the following eight items, each formatted as a minimum and maximum score of 0 to 5, respectively: cough, phlegm, chest tightness, and breathlessness going up hills/stairs, activity limitations at home, confidence leaving home, sleep, and energy. Individual item scores are summarized to provide a total CAT score that can range from 0 (floor) to 40 (ceiling).

Statistical analysis

Internal consistency of the CAT questionnaire was tested by Cronbach's α coefficient analysis. Correlation analysis between the CAT score and mMRC dyspnea scale was performed, so as correlation between CAT score and pulmonary function measures [FEV_1 (L, %), FVC (L, %), FEV_1/FVC]. Test-retest analysis obtained as correlation analysis between CAT scores in two time points, was performed by the same investigators (physicians). Differences between continuous variables were tested by using Student's *t* test, ANOVA for variables with normal distribution, or Mann-Whitney *U* test or Kruskal-Wallis nonparametric ANOVA for parameters which distribution deviated from normal Gaussian distribution pattern. Differences in frequency of categorical variables were tested with χ^2 test. Correlation analysis performed by using Spearman's nonparametric correlation methods. All differences were set at 0.05 alpha.

Results

From May 2017 to January 2018, 140 patients with COPD completed the CAT questionnaire and mMRC dyspnea scale, and 20 patients completed the CAT test in two time points, performed by the same investigator (physician). General characteristic of subjects (mean age 64.4 ± 9.3 years; 84 men and 56 women) are summarized in Table 1. The majority of subject were ex-smokers (n = 82; 60%), and the rest were active smokers (n = 58; 41%). There were no subjects who never smoked. The mean body mass index (BMI) was 26.6 ± 5.4 kg/m^2. Average FEV_1 was 47.6 ± 19.1% which indicated moderate to severe airflow limitation. Average mMRC score was 1.93 ± 1.11 and average CAT was 19.5 ± 8.9, which implied that patients had more symptoms and more pronounced breathlessness (Table 1).

The Cronbach's α was 0.887 for the CAT test. Neither Cronbach's α item deleted value was not larger than basic value of 0.887, so we concluded that all questions are consistent with the questionnaire topic. We found significant positive correlation between the CAT score and mMRC score ($\rho = +0.570$; $p < 0.001$). The CAT score showed weak but significant negative correlation with FVC (L): $\rho = -0.274$; $p < 0.01$) and FEV_1 (L): (-0.214; $p < 0.05$), but did not correlate with any other pulmonary function measure. Test-retest analysis showed good correlation between CAT scores in two time points (Spearman's $\rho = 0.681$; $p < 0.01$).

Table 1

General anthropometric, demographic, pulmonary function data and average modified Medical Research Council Dyspnea Scale (mMRC) and Chronic Obstructive Pulmonary Disease Assessment Test (CAT) score in the study population

Parameter	Values
Age (years), mean ± SD	64.4 ± 9.3
Gender (male/female), n (%)	84/56 (60/40)
Nonsmoker/ex-smoker/current smoker, n (%)	0/82/58 (0/59/41)
BMI (kg/m^2), mean ± SD	26.6 ± 5.4
Post-BD FEV1 (L), mean ± SD	1.27 ± 0.59
Post-BD FEV1 (%), mean ± SD	47.6 ± 19.1
Post-BD FVC (L), mean ± SD	2.73 ± 0.92
Post-BD FVC (%), mean ± SD	81.9 ± 21.0
Post-BD FEV1/FVC, mean ± SD	46.2 ± 12.3
mMRC score, mean ± SD	1.93 ± 1.11
Total CAT score, mean ± SD	19.5 ± 8.9

BMI – body mass index; BD-FEV_1 – bronchodilator-forced expiratory volume in the first second; BD-FVC – bronchodilator-forced volume vital capacity; SD – standard deviation.

Next, patients were classified according to the GOLD stage (I–IV). In the GOLD stage groups we compared different general, anthropometric, clinical and pulmonary function parameters, exacerbation status and maintenance therapy (Table 2). There was no difference in distribution of ex-smokers and smokers, and cumulative smoking status expressed in pack/years among GOLD I–IV groups. Patients with longer disease duration tended to be in higher GOLD stage groups, but there was no significant difference. Average COPD duration was from 4 years in the GOLD I group to 8.5 years in the GOLD IV group. Patients with higher GOLD stage had significantly more acute exacerbation episodes (GOLD III and IV groups compared to II and I), and also higher number of exacerbations requiring hospitalization (especially the GOLD IV group compared to other three groups). Regarding maintenance therapy higher percentage of patients used long acting muscarinic antagonists (LAMA) and inhaled glucocorticoid (ICS)/long acting bronchidilators (LABA) in higher GOLD stage groups. The mMRC breathlessness score was highest in the GOLD IV group compared to other three GOLD groups. On the contrary, the CAT total score did not show exact regularity with the GOLD stage change (Table 2).

Table 2

Demographic, clinical and functional characteristics, exacerbations and therapy of the study population related to the GOLD stadium classification

Parameter	GOLD I (n = 10)	GOLD II (n = 48)	GOLD III (n = 53)	GOLD IV (n = 30)	*p*
Age, years	63.4 ± 6.4	65.2 ± 9.8	65.7 ± 8.4	58.8 ± 9.3[c]	0.041
Smoking status, (smoker/ex smoker), n (%)	5/5 (8.6/6.0)	19/29 (32.8/34.9)	22/31 (37.9/37.3)	12/18 (20.7/21.7)	0.945
BMI (kg/m^2), mean ± SD	30.0 ± 6.7	27.7 ± 5.5	26.8 ± 4.7	23.2 ± 4.9[a]	0.038
Pack years, mean ± SD	42.1 ± 20.0	33.8 ± 17.4	34.6 ± 17.3	33.7 ± 20.5	0.725
COPD duration, years*	4.0 (3.00–9.50)	6.0 (4.0–9.0)	8.0 (4.0–12.0)	8.5 (5.50–13.50)	0.137
Acute exacerbation, n*	1.00 (0.0–1.0)	1.00 (0.0–2.0)	2.00 (1.0–3.0)[aa]	3.00 (1.5–3.0)[aaa,bb]	< 0.001
Exacerbation requiring hospitalization, n*	0 (0–0)	0 (0–0)	0 (0–1)	1 (0–2)[a,b]	0.006
FEV1 (%), mean ± SD	86.6 ± 9.9	60.8 ± 8.2[aaa]	39.7 ± 5.8[aaa,bbb]	24.4 ± 3.4[aaa,bbb,ccc]	< 0.001
FEV1 (L), mean ± SD	2.38 ± 0.63	1.60 ± 0.47[aaa]	1.08 ± 0.29[aaa,bbb]	0.69 ± 0.17[aaa,bbb,ccc]	< 0.001
FVC (%), mean ± SD	107.6 ± 11.1	94.3 ± 13.5	78.6 ± 17.3[aaa,bbb]	59.4 ± 15.4[aaa,bbb,ccc]	< 0.001
FVC (L), mean ± SD	3.64 ± 0.66	3.05 ± 0.91	2.63 ± 0.84[aa]	2.10 ± 0.674[aaa,bbb,ccc]	< 0.001
FEV1/FVC, mean ± SD	65.1 ± 8.5	53.2 ± 8.9[aaa]	42.9 ± 8.6[aaa,bbb]	34.4 ± 9.4[aaa,bbb,ccc]	< 0.001
LAMA therapy, n (%)	5 (71)	31 (93.9)	37 (97.4)	20 (100)	0.024
LABA therapy, n (%)	1 (14.3)	6 (18.2)	7 (18.4)	4 (20.0)	0.852
ISC/LABA therapy, n (%)	3 (42.9)	17 (51.5)	30 (78.9)	16 (80.0)	0.025
mMRC dyspnea score, mean ± SD	1.00 ± 0.82	1.70 ± 1.10	2.11 ± 1.08	2.50 ± 0.95[aa,b]	0.009
CAT total score*	15.0 (9.0–21.0)	18.5 (10.5–24.5)	21.0 (16.0–25.0)	20.0 (15.0–28.0)	0.314

GOLD – Global initiative for Chronic Obstructive Lung Disease; **BMI – body mass index; COPD – chronic obstructive pulmonary disease; FEV_1 – forced expiratory volume in the first second; FVC – forced volume vital capacity; LAMA – long acting muscarinic antagonist; LABA – long acting bronchodilators; ICS – inhaled glucocorticoid; mMRC – modified Medical research council; CAT – COPD assessment test.**

***parameters with non-normal distribution presented as median (25th–75th percentile) values; *p* from parametric (ANOVA) or from non-parametric (Kruskal-Wallis) tests; a, b, c letters indicate significant difference compared to the GOLD I, the GOLD II and the GOLD III group, respectively (one letter – $p < 0.05$, two letters – $p < 0.01$, three letters – $p < 0.001$).**

Relation between the CAT score and presence of comorbidities, all and cardiovascular, and number of exacerbation/year are summarized in Table 3.

Table 3

CAT score values, comorbidities and exacerbation rates

Impairment	Patients n (%)	mean ± SD	*p*
Comorbidities			
none	70 (50)	17.2 ± 8.5	0.184
At least one	70 (50)	20.1 ± 10.2	
CVB comorbidity			
none	59 (42)	18.2 ± 9.0	0.539
At least one	81 (58)	16.9 ± 8.7	
Exacerbations			
none	26 (18)	12.0 ± 6.4	
1	33 (24)	17.3 ± 10.2	0.003
≥ 2	81 (58)	20.0 ± 8.3[aa]	

CAT – Chronic Obstructive Pulmonary Disease Assessment Test; CVB – cerebrovascular burden.

***p* from ANOVA ([aa] $p < 0.001$ vs. group without exacerbation).**

There was no significant difference in the CAT score between subjects with or without investigated comorbidities. On the contrary, an increase in exacerbation number was related consistently with higher CAT score ($p < 0.01$), so patients with 2 or more exacerbations during one year had significantly higher CAT score (Table 3). We also compared CAT scores between body mass index (BMI subgroups, but neither any regularity nor statistical significance were found.

Discussion

The study demonstrated good internal consistency and reliability of the CAT score in a population of COPD patients in Serbia. The CAT correlated moderately with the mMRC scale, did not differ significantly across spirometric GOLD stages and was higher in patients who experienced frequent exacerbations.

The CAT is a short (8-item), self-administered questionnaire developed by Jones et al. [5, 8] for the purpose of measuring health status of patients with COPD. It was derived from the data from three international observational

prospective studies including 1,503 COPD patients from Belgium, France, Germany, the Netherlands, Spain and the USA following rigorous methodological approach and was subsequently validated in the subgroup of patients from the USA. This study showed excellent consistency of the questionnaire with the Cronbach's alpha of 0.88 and a good reliability [8]. Soon after it was developed, the CAT was incorporated into the GOLD guidelines as a part of a multidimensional assessment of COPD patients. Currently, the CAT is the preferred method for symptom assessment over traditionally used the unidimensional mMRC scale that measures only breathlessness, as it is more comprehensive (GOLD). Also, the CAT demonstrated a very good correlation with the SGRQ that is commonly used to access the impact of COPD on health status in clinical trials but is too complex for use in a busy every day practice [8].

Since the CAT questionnaire was developed and validated in English language it is possible that cultural, social, and linguistic differences may affect its performance in other populations. Hence, after its publication in 2009, the CAT has been translated and validated in various countries including Japan [11], Indonesia, Korea, Vietnam [12], Thailand [13], Brazil [14], Turkey [15], Iran [16] and Arabic speaking countries [17]. To our knowledge our study was the first that validated the use of the CAT in Serbian language.

We demonstrated that the Serbian version of CAT has high internal consistency with Cronbach's alpha 0.88 that is identical to original version of CAT [8] and comparable to other validation studies in which Cronbach's alpha ranged from 0.73 to 0.98 thus exhibiting high item correlation [16, 18]. The demographic characteristics of our study population were similar to derivation cohort [8] with 60% men, mean age 64 years, but our patients had more severe airway obstruction (mean FEV1 47.6 ± 19.1% predicted compared to 52.3 ± 18.9% predicted in the US and 57.8 ± 19.9% predicted in the EU cohort). The mean values of the CAT score was 19.5 ± 8.9 indicating that patients had high symptom burden and pronounced breathlessness which is comparable to CAT scores in studies from Belgium, France, Germany, US, Portugal and Asian population [12, 14, 19].

Test-retest reproducibility measured at two time points in our study was good (Spearman's $\rho = 0.681$) and consistent with other validation studies. When compared to other important functional and physiological variables, the CAT correlated moderately to the mMRC scale ($\rho = +0.57$) and weakly to FEV1 (ρ -0.214). This is in line with previous studies in which the correlation between the CAT and mMRC scale ($\rho = 0.29$–0.61) and FEV1 ($\rho = -0.56$–-0.23) was found to be moderate at best [18]. Although in our study more severe COPD patients (the groups 3 and 4) had higher CAT scores the difference between the COPD groups was not significant. By contrast, a cross-sectional European study [19] showed a constant increase of the CAT score across COPD stages with 3 points difference between the classes.

In our study, the CAT was positively related to number of exacerbations. Frequent exacerbators (≥ 2 exacerbations) had higher CAT scores compared to non exacerbators (20.0 ± 8.3 vs. 12.0 ± 6.4, respectively). Previous studies have also demonstrated that infrequent exacerbators have lower values of the CAT score compared to patients with ≥ 2 exacerbations [20, 21]. In addition, CAT values are shown to be higher in patients experiencing exacerbation compared to stable patients with a mean difference of 4.7 units between the groups [8, 19, 22].

We found no difference in CAT scores in patients with and without comorbidities. This is consistent with study by Kwon et al. [12] in Asian population but differs from large European study where presence of 3 or more comorbidities has been associated with higher CAT scores [19]. This may be due to a difference in sample size, as study by Jones et al. [12] included significantly higher number of patients that allowed subgroup analysis. Similarly to aforementioned studies we found no difference in CAT scores between patients with and without cardiovascular disease. Also, in contrast to previous data that showed that patients with lower BMI have higher CAT scores [12] in our study the CAT score did not differ across BMI groups.

Our study has several limitations. First, the study included COPD patients from two academic pulmonary hospitals that are not necessarily generalizable to all COPD patients in Serbia. Second, although number of patients is comparable to other questionnaire validation studies, our study was likely underpowered to detect between group differences which may explain the observed dissimilarities (such as non-significant differences in CAT values across GOLD stages and BMI groups) when compared to larger studies. Nevertheless, this is the first study to validate the CAT in Serbian language that confirmed its reliability and consistency.

Conclusion

The Serbian version of the CAT is an easy to administer and reliable tool that could be used in everyday clinical practice for assessment of health status in Serbian COPD patients.

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