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The Association Between Six-Minute Walk Test and One Minute Sit to Stand Test in Patients with Acute Exacerbations Of COPD

Akut Alevlenmesi Olan KOAH Hastalarında Altı Dakika Yürüme Testi ile Bir Dakika Otur Kalk Testi Arasındaki İlişki

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Abstract

Aim: Acute exacerbations of chronic obstructive pulmonary disease (AECOPD) are a major complication of COPD and a leading cause of hospitalization, detrimentally affecting functional exercise capacity. The 6-minute walk test (6MWT) is a reliable measure of exercise capacity in chronic lung diseases. Conversely, the 1-minute sit-to-stand test (1STST) offers a simpler assessment of physical function. The aim was to demonstrate the association of functional exercise capacity assessed by 1STST and 6MWT in COPD patients with acute exacerbation.

Material and Method: Thirty-seven hospitalised patients with an acute exacerbation of COPD (91% male, age: 66.9±7.3, BMI: 27.1±6.2) were assessed using lung function testing (spirometer), functional exercise capacity (6-minute walk test and 1-minute sit and stand test) and dyspnoea perception (Modified Medical Research Council scale). Parameters such as heart rate, oxygen saturation, and perceived dyspnea (via the modified Borg scale) were monitored during tests.

Results: The results showed a significant correlation between 6MWT and 1STST performance (r=0.656, p<0.001). Notably, end-tidal oxygen saturation differed between tests, with the 6MWT showing higher end-tidal dyspnea scores. During recovery, 1STST induced increased heart rate and decreased oxygen saturation. Both 6MWT and 1STST were negatively associated with age and MMRC. Positive correlations were observed between 6MWT and FEV1(L) and PEF(L).

Conclusion: Similar to the 6MWT, the 1STS test may be used to evaluate how well patients with AECOPD perform during functional exercise. We propose that the 1STST is a suitable alternative to the 6MWT for the assessment of functional exercise performance during hospitalization in AECOPD patients.

Keywords: Acute exacerbations, chronic obstructive pulmonary disease, six-minute walk test, 1-minute sit to stand test, exercise capacity.

Öz

Amaç: Akut alevlenme dönemleri, Kronik obstrüktif akciğer hastaları (KOAH) için önemli bir komplikasyon ve hastaneye yatışın önde gelen nedenlerinden biridir. Bu durum fonksiyonel egzersiz kapasitesini olumsuz yönde etkiler. Altı dakika yürüme testi (6DYT) kronik akciğer hastalıklarında egzersiz kapasitesinin değerlendirilmesinde kullanılan güvenilir bir testtir. Öte yandan, 1 dakika otur-kalk testi fiziksel fonksiyonun daha basit bir değerlendirmesini sunar. Bu çalışmada akut alevlenen KOAH hastalarında, fonksiyonel egzersiz kapasitesinin değerlendirilmesinde kullanılan 6DYT ve 1 dakika otur kalk testinin arasındaki ilişkinin gösterilmesi amaçlanmıştır.

Gereç ve Yöntem: Hastanede yatan 37 akut alevlenen KOAH hastasına (%91 erkek, yaş:66.9±7.3, Bki: 27.1±6.2) solunum fonksiyon testi (spirometre), fonksiyonel egzersiz kapasitesi (altı dakika yürüme testi ve 1 dakika otur kalk testi), dispne algısı (Modifiye Medical Research Council) ölçeği ile değerlendirildi. Testler sırasında kalp hızı, oksijen satürasyonu ve algılanan dispne parametreleri (modifiye Borg ölçeği) izlendi.

Bulgular: 6DYT ile 1 dakika otur kalk testinin performansı arasında anlamlı bir korelasyon bulunmuştur (r=0.656, p<0.001). Özellikle, test sonu oksijen satürasyonu testler arasında farklılık göstermiştir ve test sonu bulgularında 6DYT daha yüksek dispne algısına sebep olmuştur. Toparlanma sırasında, 1 dakika otur kalk testinin vital bulgularında kalp hızında daha fazla artış ve oksijen satürasyonunda daha fazla düşüş görülmüştür. Hem 6DYT hem de 1 dakika otur kalk testi yaş ve MMRC parametreleri ile negatif ilişkiliydi. 6DYT ile FEV1(L) ve PEF(L) arasında pozitif korelasyon gözlenmiştir.

Sonuç: Altı-DYT gibi, 1 dakika otur kalk testi de akut alevlenen KOAH hastalarının fonksiyonel egzersizin değerlendirilmesi sırasında kullanılabilir. Akut alevlenen KOAH hastalarında hastanede yatış sırasında fonksiyonel egzersiz performansının değerlendirilmesi için 1 dakika otur kalk testini 6DYT'nin yerine uygun bir alternatif olarak öneriyoruz.

Anahtar Kelimeler: Akut alevlenme, Kronik obstrüktif akciğer hastalığı, 6-dakika yürüme testi, 1 dakika otur kalk testi, egzersiz kapasitesi

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a heterogeneous lung disease characterized by airflow obstruction, poor pulmonary gas exchange and hyperinflation. ^[1] Acute exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD), a serious complication of COPD and the most common cause of hospital admission, has many adverse effects such as worsening quality of life, accelerated disease progression, increased hospitalizations, morbidity and mortality. ^[1,2] Acute exacerbation of COPD leads to acute reductions in lung function and acute increase in symptoms and a consequent decrease in skeletal muscle function and functional exercise capacity.^[3] Several tests are used to assess the functional exercise capacity of patients with lung disease. The 6-minute walk test (6MWT) is a valid and reliable measure of exercise capacity in patients with chronic lung disease. The 6MWT for COPD is a simple, inexpensive and standardized test.^[4] However, as the 6MWT requires familiarization and is time consuming, many more practical alternative tests have been proposed. One of these alternative tests is the one-minute sit to stand test (1STST). ^[5] The 1STST requires less space and time than the 6MWT and is similarly a self-paced test that can be influenced by the patient's motivation. In contrast to the 6MWT, more specific muscle groups are involved in this test.^[6] Although the 1STST is an appropriate test for patients with stable COPD, little is known about its psychometric properties clinical implications for patients with AECOPD.^[7] Previous studies have investigated whether the 6MWT and the 1STST can be used as alternatives to each other in patients with stable COPD and in people with advanced lung disease, and have also compared the cardiorespiratory responses of the two tests.[6,8-10] In the literature, no data evaluating studies in AECOPD patients were found. This research was therefore created to examine the association between functional exercise capacity as measured by the 6MWT and 1STST in patients with acute exacerbation of COPD.

MATERIAL AND METHOD

The study was carried out with the permission of Necmettin Erbakan University Meram Faculty of Medicine Pharmaceutical and Non-medical Device Ethics Committee (Date: 01.07.2022, Decision No: 157). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. An informed consent form was signed by all patients.

Patients

Patients with AECOPD hospitalized in Necmettin Erbakan University Meram Medical Faculty Chest Diseases Department between August 2022 and May 2023 were included in our study.

Inclusion Criteria

- Patients who were hospitalized due to acute exacerbation of COPD
- Patients of all genders, ranging in age from 18 to 75 years, were included.

Exclusion Criteria

- Patients with orthopedic or neurological problems that may prevent assessment,
- · Patients with malignancy,
- Patients with advanced heart problems such as acute coronary syndrome, stable angina pectoris, severe arrhythmias, decompensated heart failure,
- Those who wanted to leave the study voluntarily were excluded.

Thirty-seven COPD patients (3 female, 34 male) with acute exacerbating chronic obstructive pulmonary disease and hospitalized from Necmettin Erbakan University were included in the study.

Study Design

The patients were evaluated on the day they were admitted to the hospital. Exercise tests and respiratory functions of the patients were evaluated on the first day. Dyspnea, fatigue and leg fatigue were assessed using the modified Borg scale^[11] before (pretest), immediately after (end-test) and 1 minute after (recovery phase) the 6MWT and 1STST. We utilized the empirical model as previously explained to calculate the BODE index: The patients were given points ranging from 0 (lowest value) to 3 (maximum value) for each threshold value of FEV₁, distance walked in six minutes, and score on the modified Medical Research Council (MMRC) dyspnea scale. The options for body mass index were 0 or 1. The points for each characteristic were summed together to create a BODE index for each patient that varied from 0 to 10.^[12]

Pulmonary Functions

Pulmonary function test measurements (EasyOne Pro Lab, Switzerland) were performed according to American Thoracic Society (ATS) and European Respiratory Society (ERS) criteria.^[13] Pulmonary function tests measure forced vital capacity (FVC), which is the volume of air during a forced and rapid expiration, the volume of air inhaled in the first second of a forced expiration (FEV₁), the ratio of forced expiratory volume to forced vital capacity in the first second (FEV₁/FVC), peak expiratory flow rate (PEF) and forced vital capacity in mid-expiration (FEF_{25-75%}). The test was performed in an upright sitting position on a chair and repeated until the test was successful.^[14]

Dyspnea

The Modified Medical Research Council (MMRC) dyspnea scale is used to evaluate shortness of breath during activities of daily living. It is a scale scored between 0-4 with the value that best describes the perception of dyspnea out of five statements about dyspnea. As the person's breathlessness worsens, the score increases. It can be assessed either individually or through questioning by the interviewer.^[15]

Six-Minute Walk Test

Exercise capacity was evaluated using the six-minute walk test (6MWT) according to the ATS criteria.^[16] The test was conducted in a 30-meter long corridor. Heart rate, oxygen saturation, blood pressure, respiratory frequency, dyspnea, fatigue and quadriceps

Sit to Stand Test

The 1STST was performed with a 46 cm standard-height chair without an armrest. The patient was allowed to sit upright in the chair. The patient sat with knees and hips flexed to 90°, feet flat on the floor at hip-width, and hands resting on hips. Each time the person rose from the chair was validated to check whether the full sit-stand-sit sequence was achieved. The number of sit and stand for 1 minute was determined manually. Heart rate, oxygen saturation and dyspnea values were recorded before and after the test.^[17]

Statistical Analysis

Statistical analysis was performed using SPSS version 26.0 (SPSS, Chicago, IL, USA). Normality of the data was tested by Kolmogorov Smirnov test. Data are expressed as mean (±SD) or median (minimum-maximum). Paired Samples t-test (for normally distributed data) and Wilcoxon test (for non-normally distributed data) were used to compare results and distances between the two tests. Correlations between the 6MWT distance and number of 1 STST and demographic/clinical characteristics were calculated using Pearson correlation coefficients under parametric conditions and Spearman correlation coefficients under nonparametric conditions. Bland-Altman plot was used to evaluate the agreement between 6MWT distance and 1STST test. We calculated the sample size considering a minimum acceptable correlation coefficient of 0.65. Assuming an alpha error of 0.05 and 95% power, a minimum of 24 AECOPD patients were sufficient for the model. The statistical significance level for all analyses was defined as p<0.05.

RESULTS

Thirty-seven patients with acute exacerbation of COPD who agreed to be included in the study and met the inclusion criteria participated in the study (Figure 1). Demographic characteristics, pulmonary functions, BODE index (total score) values, the distance of the six-minute walking test, the number of one-minute sit-stand tests and the percentage of the distance of the six-minute walking test of the patients are presented in Table 1. The comorbidities present in the patients were diabetes mellitus (11 patients), hypertension (11 patients), coronary artery disease (3 patients), stroke (1 patient) and hepatitis (one patient). Nine of the patients reported that they were still active smokers. Acute exacerbated COPD was mild in 5% of patients (GOLD I), moderate in 38% (GOLD II), severe in 22% (GOLD III) and very severe in 35% (GOLD IV). Most patients (73%) were "at high risk and with high symptom burden" (GOLD D). All patients completed both exercise tests without any problems.

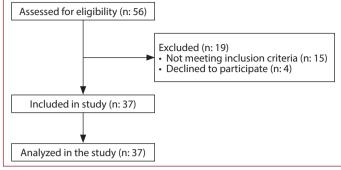


Figure 1. Consort flow chart

	Mean±SD	Min-Max
Age (years)	66.9±7.3	46-79
Weight (kg)	73.3±17.0	35-108
Height (cm)	164.4±6.3	150-179
BMI (kg/m²)	27.1±6.2	13.3-38.7
Length of hospitalization (day)	9.1±4.5	3-30
Duration of disease (year)	10.3±8.2	1-28
Hospital admissions in last year (n)	4.1±3.3	0-12
Emergency visit in last year (n)	2.9±3.7	0-15
Smoking (pack-years)	52.4±43.8	12-200
FEV1 (L)	1.1±0.6	0.3-3.4
FEV1 (%)	44.0±21.6	13-95
FVC (L)	1.8±0.8	0.4-4.5
FVC (%)	54.1±23.7	15-113
FEV1/FVC (%)	63.0±15.9	29.4-100
FEF _{2575%} (L)	0.8±0.7	0.1-3.4
FEF _{2575%} (%)	38.2±31.6	7-162
PEF (L)	3.3±1.5	1.5-8.4
MMRC (1-4)	3.0±0.6	2-4
BODE index	5.9±2.0	1-9
GOLD stage (I-IV)	2.8±0.9	1-4
6MWT (m)	205.5±108.6	28-420
6MWT (% predicted)	38.6±19.2	5.1-78.6
1STST (n)	15.6±6.3	3-27

BMI, body mass index; Liltres; cm: centimetre; kg: kilogram; m:metre; FEV:: Forced expiratory volume in 1 s; FVC: forced vital capacity; FEV:/FVC: ratio of forced expiratory volume to forced vital capacity in the first second; FEF_{2575%}: forced mid-expiratory flow rate; PEF: peak expiratory flow rate, MMRC: Modified Medical Research Council dyspnea scale, 6MWT: Six-minute walk test, 1STST: One minute sit to stand test.

The before-test, end-of-test and recovery mean values of heart rate, oxygen saturation and dyspnea perception for both exercise tests are shown in **Table 2**. There was a significant difference between heart rate and dyspnea values among the baseline physiologic parameters (p<0.05). End-of-test heart rates were similar in both tests and there was no significant difference (p>0.05). There was a significant difference (p>0.05). There was a significant difference between the tests in end-of-test oxygen saturation (p<0.05). Oxygen saturation was much lower at the end of 6MWT compared to 1STST. In terms of end-test dyspnea scores, 6MWT scores were higher than 1STST scores. There was a significant difference between heart rate and oxygen saturation values in the recovery phase (p<0.05). In the recovery phase, heart rate was much higher and oxygen saturation was lower in the 1STST.

Table 2. Cardiorespiratory parameters							
	6MWT (Mean±SD)	1STST (Mean±SD)	р				
$^{\delta}$ Heart rate (beats/m	in)						
Baseline	86.2±16.2	90.6±15.6	0.012*				
End	106.2±16.8	106.8±16.5	0.812				
Recovery	93.1±16.0	100±14.2	0.003*				
^v Oxygen saturation	(%)						
Baseline	93.1±3.2	92.4±3.4	0.352				
End	88.3±6.8	91.4±3.8	0.001*				
Recovery	92.9±3.0	91.8±3.3	0.043*				
⁶ Dyspnea (Borg scale; 0-10)							
Baseline	1.7±1.3	2.1±1.2	0.0 42*				
End	5.7±1.9	5.0±1.6	0.038*				
Recovery	4.5±1.9	3.9±1.6	0.103				
γ: Wilcoxon signed rank test,δ: paired sample t test, 6MWT: six-minute walk test, 1STST: one minute							

sit to stand test, *p<0.05

The relationships between clinical variables and 6MWT and 1STST are shown in **Table 3**. 6MWT and 1STST test were statistically significantly associated (r=0.656, p<0.001, **Table 3**). Both 6MWT and 1STST were significantly negatively associated with age and MMRC (p<0.05). 6MWT was significantly negatively associated with smoking pack-years (p<0.05). There were significant positive correlations between 6MWT and FEV₁(L) and PEF (L) (p<0.05). No statistically significant correlations were found between the 6MWT and 1STS tests; height, weight, BMI, resting and activity Borg scale, and except for pulmonary function parameters. The agreement between 6MWT and 1STST is shown in Bland-Altman plots (**Figure 2**). The mean difference between the 6MWT distance and the number of 1STST was -189.9, and the limits of agreement were -83.4 and -292.4.

Table 3. Correlation between clinical variables and 6MWT and 1STST							
	6MWT		1STST				
	r	р	r	р			
Age (years)	-0.443	0.006	-0.377	0.021			
Weight (kg)	0.006	0.970	-0.148	0.382			
Height (cm)	0.177	0.294	-0.081	0.632			
BMI (kg/cm²)	-0.056	0.740	-0.130	0.442			
Smoking (packxyears)	-0.353	0.044	-0.169	0.348			
Resting Borg Scale (1-10)	-0.223	0.186	-0.143	0.398			
Activity Borg scale (1-10)	-0.198	0.239	-0.40	0.815			
MMRC (1-4)	-0.663	<0.001	-0.427	0.008			
FEV1 (L)	0.377	0.021	0.119	0.482			
FEV1 (%)	0.185	0.272	-0.023	0.891			
FVC (L)	0.277	0.097	-0.046	0.785			
FVC (%)	0.160	0.344	-0.087	0.607			
FEV1/FVC (%)	0.097	0.567	0.073	0.670			
FEF _{2575%} (L)	0.218	0.195	-0.044	0.795			
FEF _{2575%} (%)	0.101	0.551	-0.085	0.617			
PEF (L)	0.342	0.038	0.008	0.960			
6MWD (m)			0.656	<0.001			
1STST (n)	0.656	<0.001					

*Pearson and spearman correlation coefficients, BMI, body mass index; L: litres; FEV: Forced expiratory volume in 1 s; FVC: forced vital capacity; FEV₄/FVC: ratio of forced expiratory volume to forced vital capacity in the first second; FEF₂₃₇₅₈; forced mid-expiratory flow rate; PEF: peak expiratory flow rate, MMRC: Modified Medical Research Council dyspnea scale, 6MWT: Six-minute walk test, 1STST: One minute sit to stand test,p<0.05

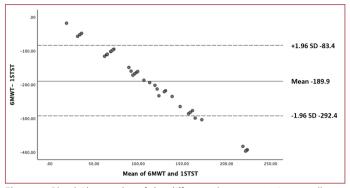


Figure 2. Bland-Altman plot of the difference between 6-minute walk test (6MWT) and 1-minute sit-to-stand test (1STST) plotted against the mean of 6MWT and 1STST.

DISCUSSION

The number of published studies measuring functional status in COPD has increased rapidly in recent years but such studies in patients with AECOPD are limited. This study demonstrated a significant relationship between functional exercise capacity as assessed by the 6MWT and the 1STST in patients with AECOPD. A relationship was observed between the number of 1STST repeated and distance walked in the 6MWT. However, the physiological parameters differed significantly between the tests. Among the physiological parameters at baseline, there was a significant difference between heart rate and dyspnea scores. At the end of the test, the 6MWT, oxygen saturation was lower and the perception of dyspnea was higher compared to the 1STST. During the recovery phase, heart rate was much higher and oxygen saturation was lower in the 1STST. We also found that MMRC was the main factor influencing the results of both tests.

The present study shows that there is a statistically significant relationship between the distance walked in the 6MWT and the number of repetitions of the 1STST. In patients with exacerbation of COPD, the acute increase in respiratory load during exacerbations causes breathlessness even when engaging in low-intensity activities, which lowers their functional exercise tolerance.^[3] The current findings are similar to previous studies in patients with stable COPD which found strong correlations between the 6MWT and the 1STST,^[6,8,10,18] as well as a study in patients with acute exacerbations of COPD.^[7] The significant correlation between the distance walked and the number of repetitions means that both tests are measuring functional exercise performance and that the statistical power of the correlations is high.

In this study, the baseline physiological parameters of heart rate and dyspnea were significantly different in both tests. Previous studies have shown that the baseline physiological parameters of the tests are similar.^[8,10] These studies were carried out in patients with stable COPD. We believe that the fact that our patients were in the acute exacerbation phase may be the reason for the different result in our study.

The current study confirmed a significant decrease in end of the test oxygen saturation between the tests. The oxygen saturation was lower at the end of the 6MWT compared to the 1STST. Our patients received supplemental oxygen during both tests as they were in the acute exacerbation phase. In previous studies, patients were both stable COPD and it was unclear whether they received supplemental oxygen during testing. However, to our knowledge, only a few studies have been conducted on the assessment of oxygen desaturation with 1STST in patients with acute exacerbations of COPD.^[7] Conflicting results have been reported in the literature on the decrease in SpO₂ during 1STST. On the one hand, studies reported no significant change in SpO₂ during 1STST,^[11,12] while on the other hand, results of previous studies showed less desaturation during 1STST, similar to our study.[6,7,18] The most likely reason for this is that the 6MWT lasts longer than the 1 STST and therefore people with chronic lung disease are exposed to increased ventilatory demand, dynamic hyperinflation and a greater V/Q mismatch for a longer period of time.^[19]

In this study, 6MWT scores were higher than 1STST scores in terms of end-test dyspnea scores expressed on the modified Borg scale. In similar previous studies, dyspnea scores were similar in both tests.^[6,8,17] Dyspnea scores may have differed between the two tests due to the longer duration of the 6MWT test and the fact that patients were in the acute exacerbation phase. Patients with acute exacerbations of COPD have severe dyspnea even at rest and increased exertion during testing may result in higher dyspnea scores.

In the present study, both walking tests elicited heart rate responses but recovery heart rates were higher for the 1STST compared to the 6MWT. In a study of stable COPD patients, a greater increase in heart rate was observed after the 6MWT compared with the 1STST, and cardiorespiratory work was greater after the 6MWT. In this study, the higher heart rate after the 6MWT was explained by the longer duration of the test.^[6] In the present study, we believe that the fact that our patients were in the acute exacerbation period may be the reason why the heart rate was higher at 1STST than at 6MWT. It is possible that many factors such as hypoxaemia, dynamic hyperinflation, systemic inflammation and drug therapy present in COPD patients during the acute exacerbation period may affect the autonomic cardiac response to exercise and lead to adverse results in disease prognosis.^[20] Therefore, we suggest that COPD patients with acute exacerbations may have a higher heart rate in the recovery phase after the 1STST test. Studies are needed to investigate the physiological effects of this change in 1STST recovery parameters in COPD patients with acute exacerbations.

As shown in the present study, MMRC was significantly negatively associated with both 6MWT and 1STST. Dyspnea in patients with COPD is one of the strongest correlates of impaired exercise performance. In COPD patients experiencing an acute exacerbation, the degree of dyspnea worsens as the patient's need for ventilation grows until it reaches the ventilator's maximum capacity.^[21] When we look at other studies, 6MWT walking distance in AECOPD patients showed a strong correlation with MMRC,^[22] in another study, a correlation was found between MMRC and 30 seconds sit to stand test and 5 repetitions of sit to stand test in stable COPD patients.^[23] Exacerbations cause respiratory issues to worsen, which is compounded by a history of persistent immobility. The finding of a relationship between MMRC and the tests might point to people with worsened COPD who are becoming more immobile and experiencing more dyspnea.

The present study showed a significant positive correlation between the 6-min walk test and the lung function parameters FEV1 (L) and PEF (L) in AECOPD patients. However, there was no statistically significant correlation between the other parameters of lung function test. In contrast to our study, previous studies have found no correlation between 6MWT and 1STST and FEV1 in stable COPD patients.^[6,24] While another study carried out in patients with stable COPD found a correlation between the FVC and the 6MWT test.^[8] Although it is thought that FEV₁ is not a good predictor of functional status in COPD patients and that field tests are not complementary in assessing lung function^[25] our study has shown a result in the opposite direction. We think that the different result is due to the fact that the patients were in the acute exacerbation phase. Unfortunately, there are no studies that examined patients with an acute exacerbation of COPD that we can use to make comparisons with the results of our study. Therefore, more studies are needed on this topic in AECOPD patients.

6MWT and 1STST were not found to be statistically significantly associated with height, weight, BMI, resting and activity Borg scales. Age was correlated with 1STST and 6MWT, consistent with previous studies.^[24] It is important to recognize that the 1STST and 6MWT have different movement requirements, and the factors limiting performance may differ between the tests. There may also be differences in height between individuals, which can affect patient performance when the test is performed in a standardized chair.

Limitations

One of the limitations of our study is that we did not have the opportunity to measure peripheral muscle strengths that may affect functional performance. The fact that the majority of our patients were male meant that the genderrelated responses could not be determined.

CONCLUSION

Due to the more sensitive clinical condition of patients with AECOPD, the 1STS test can be used to assess functional exercise capacity like the 6MWT. During hospitalization, the 1STS test

can be used to assess exercise capacity in a simpler and less stressful way than the 6MWT, depending on the patient's condition. Our study may contribute to the evolving knowledge of functional testing in patients with acute exacerbations of COPD and may have important clinical implications. We propose that the 1STST is a suitable alternative to the 6MWT for the assessment of functional exercise performance during hospitalization in AECOPD patients.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Necmettin Erbakan University Meram Faculty of Medicine Pharmaceutical and Non-medical Device Ethics Committee (Date: 01.07.2022, Decision No: 157).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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