RELIABILITY AND VALIDITY OF THE SIX-MINUTE STEP TEST IN ASSESSING THE FUNCTIONAL CAPACITY OF HEMODIALYSIS PATIENTS

1 ABSTRACT

Purpose: The 6-minute step test (6MST) requires little space and a small standardized ergometer, making it more accessible and feasible in various healthcare settings, when compared to the Cardiopulmonary Exercise Test (CPET) and the 6-minute walk test (6M WT). Thus, the aim of this study is to evaluate the test-retest reliability and concurrent validity of the 6MST for assessing the functional capacity of hemodialysis patients. **Methods:** Assessments conducted included anthropometry, spirometry, 6MWT, and 6MST. These two tests were randomized and performed on alternate days. Two 6MSTs and two 6MWTs were conducted with a minimum interval of 30 minutes between them. **Results:** The study involved 32 participants, 67% men (n=22) and 33% women (n=10), with an average age of 57±13 years and body mass index (BMI) of 28.6±5.2 kg/m². The 6MST demonstrated high test-retest reliability (ICC=0.94 [95% CI; 0.85 to 0.97; p <0.001]) and a strong correlation between the number of steps performed in the 6MST and the distance covered in the 6MWT (r=0.87; p<0.001). **Conclusion:** The 6MST is reliable and valid for assessing the functional capacity of hemodialysis patients.

Keywords: Hemodialysis; Functional capacity; Reliability; Validity; Kidney Disease

2 INTRODUCTION

Chronic kidney disease (CKD) leads to permanent and irreversible physiological disturbances. Exacerbation of inflammatory factors and imbalances in muscle metabolism affect the functionality and quality of life of kidney patients[1], and may be related to disease complications[2], making it necessary to assess functional capacity through functional tests.[U1]

The maximal cardiopulmonary exercise test (CPET) is considered the gold standard for assessing exercise tolerance. However, it is not available in most centers due to the high cost and complexity of the equipment[3,4]. An alternative to CPET is the 6-minute walk test (6MWT), a widely studied, valid, and reproducible test used in different populations[4], including those with CKD. Relationships have been identified between reduced functional capacity assessed by the 6MWT and clinical and physiological

manifestations of the disease[5]. However, since the 6MWT is a field test that requires a 30-meter space, it is not always a feasible option in different settings for hemodialysis patients.[U2]

By contrast, the 6-minute step test (6MST) requires little space, and only a small standardized ergometer, making it more accessible and feasible across several healthcare settings. The 6MST has been validated in other chronic disease populations, such as those with chronic obstructive pulmonary disease (COPD) and interstitial lung disease[4]. Additionally, the 6MST shows good correlation with the 6MWT in hospitalized COPD patients, suggesting that it could potentially replace the 6MWT in hospital settings[6].[U3]

Thus, due to the limited availability of valid tests for assessing functional capacity, the 6MST emerges as an alternative for patients with CKDs. However, its psychometric properties need further investigation. Thus, this study aims to evaluate the reliability and concurrent validity of the 6MST for assessing the functional capacity of hemodialysis patients.

3 METHOD

This is a cross-sectional study approved by the Human Beings Research Ethics Committee of the Santa Catarina State University (UDESC) (certificate of ethical appreciation presentation: 23430619.4.0000.0118). The study sample consisted of hemodialysis patients of both sexes admitted for hemodialysis treatment. [U4]Inclusion criteria for the study were: (1) individuals diagnosed with CKD who had been undergoing regular hemodialysis treatment for at least 6 months; (2) aged between 20 and 75 years; (3) not experiencing worsened conditions and under medical supervision; (4) individuals who did not exhibit uncontrolled hypertension, recent ischemic heart disease (3 months or less), unstable angina, or severe cardiac arrhythmias; (5) absence of diseases that would limit the assessment protocols; (6) individuals who were not engaged in any form of physical training and/or who had not trained in the past 6 months. Exclusion criteria included: (1) inability to perform any of the study assessments (due to lack of understanding or cooperation) and (2) cardiorespiratory instability (intolerant dyspnea, angina, pallor, sweating, syncope) during the tests. All individuals included read and signed the informed consent form.

Study Design

The study involved two days of assessments, alternating with hemodialysis (HD) days. On the first day, the following were performed: medical history, anthropometric data collection, and one of the randomly assigned functional tests (6MST or 6MWT). On the second day, the other functional test (6MST or 6MWT) was randomly assigned. Randomization was carried out by drawing lots.[U5]

Anthropometric Assessment: Body weight was measured using a bioimpedance scale (AVANUTRI®; AVA-450, Rio de Janeiro, Brazil), which was adjusted according to the patient's parameters, while height was measured with a stadiometer (Welmy®; Santa Bárbara d'Oeste, Brazil). After obtaining anthropometric values (body weight and height), the body mass index (BMI) was calculated using the formula body weight/height² (kg/m^2). Patients were classified based on their BMI as underweight (<18.5 kg/m^2), normal weight (18.5-24.99 kg/m^2), overweight (25-29.99 kg/m^2), and obese (>30 kg/m^2)[7].

Functional capacity assessment: The 6MST and 6MWT were conducted. In the 6MST, the individual was instructed to step up and down on a 20 cm step as many times as possible in 6 minutes. Use of the upper limbs for support was not allowed during the test. The highest number of steps completed was recorded for the study. Reduced exercise tolerance was defined as performing 50% or less of the predicted value, calculated using the formula proposed by Arcuri et al., 2016[8]. The 6MWT was performed in a 30-meter flat corridor, with the patient instructed to walk as far as possible in 6 minutes[9,10].

Both tests were conducted by two assessors, one to lead and the other to count the number of steps and laps. The 6MWT and 6MST followed the American Thoracic Society (ATS)[11] recommendations for the 6MWT, including standardized encouragement phrases every minute. Heart rate (HR), peripheral oxygen saturation (SpO_2), dyspnea, and lower limb fatigue were also assessed[12]. A minimum interval of 30 minutes between the first and second tests was established to allow cardiorespiratory parameters to return to baseline. Tests could be stopped if the patient experienced any limiting symptoms without stopping the timer.

Evaluation of lower limb perceived exertion and degree of dyspnea: this was assessed using the modified Borg Scale. The scale ranges from 0 to 10 points, with higher scores indicating greater lower limb fatigue or worse dyspnea[12].

Sample Size[U6]

The sample size was estimated on a two-tailed significance level of 0.05, power of 90%, 20% dropout rate, and an intraclass correlation coeficient (ICC) of 0.90, resulting in a sample size of 30 to 34 patients.

4 STATISTICAL ANALYSIS

Data were analyzed using SPSS software, version 23.0 (IBM Corporation). Descriptive and inferential statistics were used to present the data, with results expressed as means and standard deviations. A significance level of 95% ($p<0.05$) was established. The Kolmogorov-Smirnov test was used to assess data normality. In order to compare the physiological responses between the 6MST and the 6MWT, paired t-tests were used for parametric data, and the Wilcoxon test for non-parametric data.

Pearson's correlation coefficient and its non-parametric counterpart, Spearman's rank correlation coefficient, were used to evaluate the correlation between the 6MST and 6MWT, and between the variables analyzed. Intraobserver reliability was determined using the ICC for a two-way model with absolute agreement (two-way ICC) and a 95% confidence interval. ICC was interpreted according to the classification by Koo and Li[13], where ICC < 0.50 indicates poor reliability; 0.50 to 0.75 moderate reliability; 0.75 to 0.90 good reliability; and ICC > 0.90 excellent reliability. Bland-Altman plots were used to visualize the agreement between the two tests. Validity was tested with the hypothesis of an ICC $\geq$ 0.70 between the number of steps in the 6MST and the distance covered in the 6MWT.

5 RESULTS

A total of 34 patients were assessed. Of these, 2 were excluded, 1 due to visual impairment and 1 to musculoskeletal deformity. The final sample consisted of 32 hemodialysis patients, with the majority being men (67%; n=22). The average age of the

sample was 57±13 years, average body mass index (BMI) 28.6±5.2 kg/m², and average hemodialysis session duration 3.51 hours.

With respect to pulmonary function, 19 patients had normal pulmonary function, 1 obstructive pulmonary function, 4 restrictive pulmonary function, and 8 were unable to perform the three reproducible maneuvers, 3 due to persistent coughing during the test, 1 because of an open catheter dressing, and 4 who did not understand how to execute the maneuvers, leading to incomplete and unacceptable performance. None of the patients refused to participate or withdrew from the test. Sample characteristics are presented in Table 1.

The 6MST demonstrated high reliability, with an ICC of 0.94 (95% CI: 0.85 to 0.97; $p<0.001$) (Figure 1). The number of steps achieved correlated with the distance covered in the 6MST ($r=0.87$; $p<0.001$) (Figure 2). The average number of steps achieved was 97±38 in the 6MST, and the average distance covered in the 6MWT was 431±113 meters. In terms of functional capacity, 25% (n=8) showed reduced performance in the 6MST (<50% of the predicted value).

Patients climbed more steps in the second test when compared to the first (89.5 ± 37 versus 95.5 ± 38, respectively; $p=0.004$), with an average difference of 6 steps. A total of 27 patients (81%) performed better in the second test, with a 7% learning effect. The data from the first and second 6MST are shown in Figure 2, which shows a significant difference in performance between the two tests ($p=0.003$).

The physiological behavior was similar between the two 6MST in all variables except for subjective perception of dyspnea and lower limb fatigue after the test, with an average increase of 1 point in the second 6MST (Table 2).

Tables 3 and 4 present the variations in physiological parameters and subjective perception of effort during the 6MWT and 6MST. Significant differences were observed between the tests in terms of SBP, DBP, HR, and SpO2 at the end of the test. HR, SpO2, SBP, and DBP increased following the 6MST. The subjective perceived exertion at the end of the test increased by 2 and 3 points in dyspnea and lower limb weakness, respectively.

6 DISCUSSION

This study demonstrated that the 6MST is both valid and reliable for assessing functional capacity in hemodialysis patients, since it showed high test-retest reliability and a strong correlation with the distance covered in the 6MWT.[U7]

Both the 6MWT and 6MST are simple to monitor, and physical performance can be easily recorded, allowing exercise capacity to be evaluated during routine assessments[14]. They also offer significant advantages in terms of reduced costs and increased frequency of functional assessments when compared to the CPET. Considering only applicability, both the 6MST and 6MWT could be used to assess the functional capacity of different populations due to their psychometric characteristics and lower limb (LL) use. However, the 6MST has the advantage of using a cheap and portable step ergometer, which can be transported and set up in a small room or cubicle, requiring less physical space when compared to the 30-meter 6MWT circuit. Additionally, the 6MST simulates a less common and more challenging situation, namely climbing steps, for those with limitations in activities of daily living[15-17].

The high reliability of the 6MST in this study was confirmed by its consistency during application of the two tests on the same day with a minimum interval of 30 minutes. The ICC value obtained was 0.94 (ICC: 0.85 to 0.97). The improved performance in the retest is likely due to familiarization with the first test. Thus, there was a 7% learning effect, indicating that the individual needs to become accustomed to the effort required, by neuromuscular adaptation to the task and a decline in possible limiting factors[20]. This effect is also observed in the 6MWT[10].

In the present study, the 6MST was validated using concurrent validity. Correlations between the 6MST and 6MWT were observed in both absolute values and as percentages of predicted values, considering the validity hypothesis. Performance averaged 97±38 steps in the 6MST and 431±113 meters covered in the 6MWT. There was a strong positive correlation between the number of steps in the 6MST and the distance covered in the 6MWT ($r=0.87$; $p<0.001$), demonstrating that the 6MST is a valid test for assessing the functional capacity of hemodialysis patients.

Although the 6MST is not being widely used for individuals with CKD, likely due to a lack of documented measurement properties in the literature, it is important to underscore that the 6MST has been validated in several populations, such as those with COPD, to assess low physical capacity[4]. Additionally, in this same population, studies

[U8][U9]have demonstrated excellent reproducibility for the 6MST, good responsiveness, as as being a predictor for low exercise capacity and worse prognosis for these patients[4,18,19].

According to Arcuri et al.[18], the 6MST has also been deemed valid and reliable for assessing exercise tolerance in healthy individuals, where performance in the 6MST was strongly correlated with the 6MWT. The test is widely used and studied, with well-established assessment criteria for physical capacity in other populations, making it a safe point of comparison and validation for other instruments[21]. Marinho et al. demonstrated the validity and reliability of the 6MST for assessing functional capacity in individuals with advanced heart failure, using peak VO_2 in the CPET and the number of steps in the 6MST ($r=0.71$, $p<0.001$)[22].

By contrast, Silva et al. compared the 6MST and 6MWT in patients after a stroke and found that physiological responses were similar in both tests, but there was no correlation between the distance covered and the number of steps in the 6MST[23]. These discrepancies, compared to the present study, may be explained by the pathophysiology of stroke being different from metabolic and cardiorespiratory diseases, given that stroke primarily affects motor function and mobility more than the cardiorespiratory system itself.

Currently, there is no established cutoff point in the literature for discriminating hemodialysis patients with impaired functional capacity, as assessed by the 6MST. In other populations, such as those with COPD, cutoff points of <78 steps on the first 6MST and <86 steps on the second have been associated with reduced exercise capacity[4]. Ritt et al. observed that a cutoff of >105 steps is related to achieving a peak VO_2 above 20 $mL \cdot kg^{-1} \cdot min^{-1}$ in individuals with heart failure[3].

The primary goal of the 6MST as a submaximal test is to determine cardiorespiratory fitness. Similar to the 6MWT, the 6MST is safe and can be performed at submaximal effort, albeit with slightly higher energy expenditure. Costa et al. conducted both the 6MST and 6MWT on healthy, sedentary volunteers and in addition to confirming that the former is safe, found that it caused greater changes in HR without reaching HRmax, thereby confirming its submaximal nature[24].

In the present study, ventilatory and cardiovascular variables between the submaximal tests showed similar responses, demonstrating comparable demands. However, a greater ΔHR and ΔLL fatigue was observed with the 6MST compared to the 6MWT,

corroborating Costa et al. This suggests that while the 6MST is a safe submaximal test, it requires slightly more from hemodialysis patients when compared to the 6MWT.

The Borg scale scores for dyspnea increased by 4 points at the end of the test, and lower limb fatigue increased by 3 points. Significant increases in ΔLL fatigue were obtained with the 6MST when compared to the 6MWT. This could be due to the higher amount of active muscle mass involved in climbing up and down steps, in addition to mechanical differences in movement, gravity effects, and postural changes. Although this difference does not appear to affect test performance, the higher ΔHR values found with the 6MST compared to the 6MWT suggest greater cardiovascular stress, likely due to peripheral metabolic demands and postural variations involved in the test.

This is the first study investigating the use of the 6MST in hemodialysis patients, demonstrating its reliability and validity. As such, it provides a new potential use for this tool in assessing and managing the functional status of these patients. Additional research is suggested to investigate other measurement properties of the 6MST to solidify it as a functional assessment tool for patients with chronic kidney disease.

7 CONCLUSION

The 6MST is a reliable and valid tool for assessing functional capacity in hemodialysis patients and can be used to that end by healthcare professionals. Due to the learning effect observed in this population, it is recommended to perform two tests on the same day 30 minutes apart. The 6MST is effective in hemodialysis patients who exhibit systemic changes and reduced exercise tolerance. It allows for constant monitoring of cardiorespiratory variables and can be incorporated into the daily routine of clinics and healthcare services.

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