Relative and Absolute Reliability of Physical Function Measures in People with End-Stage Renal Disease

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ABSTRACT

Purpose: End-stage renal disease (ESRD) is a condition affecting multiple physiological systems, leading to a decline in physical function. Effectiveness of therapeutic interventions in people with ESRD has been assessed using various functional and activity outcome measures. The purpose of this study was to determine the relative and absolute reliability of the 6-minute walk test (6MWT), timed sit-to-stand in 30 seconds (TSS30), and maximal and adjusted activity scores (MAS-HAP, AAS-HAP) of the Human Activity Profile (HAP) in people with ESRD.

Method: A convenience sample of 25 participants (67.2 ± 14.2 years) was recruited from an outpatient dialysis unit. Relative reliability was determined using the intraclass correlation coefficient ($ICC_{2,1}$), and absolute test-retest reliability with the standard error of measurement (SEM) and minimal detectable change at the 95% confidence interval (MDC_{95}) statistics, respectively. The test-retest interval was 1 week.

Results: Relative reliability ($ICC_{2,1}$) was 0.93 for both the 6MWT and the TSS30, 0.92 for the AAS-HAP, and 0.76 for the MAS-HAP. Absolute reliability (SEM and MDC_{95}) values for the 6MWT, AAS-HAP, and TSS30 were 28 m and 77 m, 4.1 and 11.4, and 0.9 and 2.6 repetitions, respectively.

Conclusions: Our results suggest that the 6MWT, TSS30, and AAS-HAP are reliable physical function and activity outcome measures in people with ESRD. However, the magnitude of the absolute reliability statistics suggests significant within-participant variability on repeat testing in this population.

Key Words: end-stage renal disease, Human Activity Profile, reliability, 6-minute walk test, timed-sit-to-stand

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RÉSUMÉ

Objectif : L'insuffisance rénale chronique au stade ultime (IRSU) est un problème qui affecte de multiples systèmes physiologiques et qui conduit à un déclin des fonctions physiques. L'efficacité des interventions thérapeutiques chez les personnes atteintes d'IRSU a été évaluée à l'aide de divers indicateurs fonctionnels et indicateurs d'activité. L'objectif de cette étude était de déterminer la fiabilité relative et absolue d'un test de marche de 6 minutes (TM6), d'un test assis à debout de 30 secondes (TSS30) et des scores d'activité maximale et adaptée (MAS-HAP, AAS-HAP) de l'échelle d'activité (HAP) chez les personnes atteintes d'IRSU.

Méthode : Un échantillon de commodité composé de 25 participants ($67,2 \pm 14,2$ ans) a été recruté à partir d'une unité de dialyse pour patients externes. La fiabilité relative a été évaluée à l'aide d'un coefficient de corrélation intraclasse ($ICC_{2,1}$) et d'une mesure de fiabilité test-retest avec statistiques d'erreur de mesure standard (EMS) et changement minimal détectable (CMD_{95}), respectivement. L'intervalle test-retest était d'une semaine.

Résultats : La fiabilité relative ($ICC_{2,1}$) était de 0,93 pour le TM6 comme pour le TSS30, de 0,92 pour l'AAS-HAP et de 0,76 pour le MAS-HAP. Les valeurs de fiabilité absolue (EMS et CMD_{95}) pour le TM6, l'AAS-HAP et le TSS30 étaient de 28 m et de 77 m, de 4,1, de 11,4 et de 0,9, respectivement.

Conclusions : Nos résultats suggèrent que le TM6, le TSS30 et l'AAS-HAP constituent des indicateurs de résultats fiables pour la fonction physique et le niveau d'activité chez les personnes atteintes d'IRSU. Toutefois, la magnitude des statistiques de fiabilité absolue semble indiquer une variabilité considérable chez les participants individuellement lors de tests répétés auprès de cette population.

Mots clés : fiabilité, insuffisance rénale chronique au stade ultime, marche de 6 minutes, profil d'activité, test assis à debout chronométré

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INTRODUCTION

Chronic kidney disease is a progressive failure of renal function over a period of months or years. Renal replacement therapies such as haemodialysis are required in end-stage renal disease (ESRD) to delay mortality. According to a report published by the Canadian Organ Replacement Register (CORR), the rate of incident renal replacement therapy increased by 36% in Canada between 1999 and 2005 (i.e., from 119 to 162 per million population). At the end of 2005, a total of more than 32,000 Canadians registered with CORR were either on renal replacement therapy (>19,000) or living with a kidney transplant.¹

ESRD affects multiple organ systems, resulting in a constellation of symptoms including anaemia, reduction in cardiac function, changes in skeletal muscle strength, and reduced aerobic capacity.² Large declines in physical function during ESRD are attributable to reduced physical activity associated with treatment time on dialysis, metabolic changes related to the disease, and the catabolic effects of haemodialysis.^{3,4} Intervention studies assessing impact on these symptoms have employed various measures of physical performance and capacity, two constructs of the International Classification of Function, Disability and Health (ICF).⁵ Two frequently used measures assessing physical capacity in people with renal disease are the 6-minute walk test (6MWT)⁶ and the timed sit-to-stand test (TSS).^{4,7} There are several versions of the TSS test with varying timed durations or repetitions. The 30-second TSS (TSS30) has better reliability in community-dwelling older adults compared to a 10-second TSS or the time required to complete 5 or 10 sit-to-stand manoeuvres.⁸

Another measure commonly used with the ESRD population, the Human Activity Profile (HAP),⁹ assesses physical performance. Questionnaires are widely used to measure physical performance in order to characterize the population under study for appropriate generalization of the results. Measurement of physical performance is essential in people with ESRD, as normal or near-normal physical function is important to quality of life.¹⁰ The HAP is a 94-item questionnaire developed by Fix and Daughton.⁹ The items are rank-ordered according to the metabolic equivalents (METs) of the oxygen consumption of the activity. The HAP thus includes a variety of tasks ranging from “getting in and out of bed” to “jogging,” thereby minimizing any “floor” or “ceiling” effects for use in people with chronic disorders, who are likely to present with a range of functional abilities. In chronic conditions, the progression of functional decline can be gradual. It is important for physiotherapists to delineate the decline attributable to the disease process. A response of “have stopped doing this” to any HAP question could be considered indicative of impairment attributable to the disease process.

Psychometric properties of tests, such as their reliability, are important for assessing changes within and between individuals after an intervention. Physiotherapists need to be aware of the psychometric properties of the tests they select to monitor physical performance and capacity. Measurement error has two main components: systematic error and random error. The biological impact of the disease process contributes to such errors; thus, for all outcome measures, it is essential to determine test-retest reliability for each patient sub-group of interest.¹¹

Use of repeated measurements in a study design requires consistency between scores. The intraclass correlation coefficient (ICC) provides an estimate of *relative* reliability for consistency of measurement when the population under study is heterogeneous.¹² The ICC reflects a test's ability to differentiate between participants and, hence, the position of the individual relative to others in the group.¹² However, the ICC does not provide information about the accuracy of the scores for an individual. The standard error of measurement (SEM), a measure of *absolute* reliability, quantifies reliability of scores within individual participants on different occasions.¹³ The SEM can be used to calculate a minimal detectable change (MDC) score at different confidence levels. For example, in individuals with stable conditions, the MDC₉₅ provides a range of values within which a truly unchanged participant's score is expected to remain over repeat testing, at the 95% confidence level.¹⁴

The relative reliability of the 6MWT has been established by studies conducted with community-dwelling older adults¹⁵ and those living in retirement homes,¹⁶ as well as in people with chronic kidney disease expected to require dialysis,¹⁷ chronic obstructive pulmonary disease and heart failure,¹⁸ multiple sclerosis,¹⁹ stroke,²⁰ and fibromyalgia.²¹ Only one study has assessed the relative reliability of the 6MWT in people with ESRD, reporting a relative reliability of 0.96,²² and no study has yet reported its absolute reliability. We were unable to find any studies assessing either relative or absolute reliability of the TSS30 or HAP in people with ESRD. The purpose of our study, then, was to determine the relative reliability (reflected by ICC values) and absolute reliability (reflected by SEM and MDC₉₅) of the 6MWT, TSS30, and HAP in people with ESRD stable on dialysis.

METHODS

Study Design

This was a test-retest reliability study with all outcome measures carried out on two occasions, 1 week apart, in an ambulatory-care hemodialysis unit. The 6MWT and TSS30 were administered by the same observer immediately prior to scheduled haemodialysis sessions, which remained unchanged for study partici-

pants. Participants completed the HAP questionnaire during their dialysis sessions, with help from the trained physiotherapy assistant as required.

Participants

A required sample size of 20 was calculated, based on an alpha level of 0.05, statistical power of 80%, and a correlation of >0.60 . This calculation was based on a figure from Donner and Eliasziw using a single observer and two observations.²³ Five additional participants were recruited to maintain sample size in the event of dropouts or problems with data collection. Individuals receiving routine physical therapy intervention in an ambulatory-care hemodialysis unit were screened by the treating physical therapist for the following inclusion criteria: (1) receiving haemodialysis therapy for more than 3 months; (2) able to speak and understand English; (3) medically stable; (4) free of exertional or resting angina; and (5) free of any orthopaedic or neurological conditions that would preclude them from performing the 6MWT or TSS30. The University of Western Ontario's Ethics Review Board approved the study, and all participants provided written informed consent prior to participation.

Outcome Measures

6-Minute Walk Test²⁴

The 6MWT is a self-paced test. Participants are asked to walk as far as they can in 6 minutes at a "brisk but comfortable" pace. Participants are allowed to stop if necessary and continue when ready. The distance covered in 6 minutes is measured to the nearest metre. The test-retest relative reliability ($ICC_{2,1}$) reported for people with ESRD is 0.96.²² The 6MWT has been validated against VO_{2max} in this population ($r = 0.56$ to 0.62).^{25,26}

Timed Sit-to-Stand^{4,7}

The TSS30 is a self-paced test. Participants are asked to complete as many full stands as possible in 30 seconds, starting from a sitting position in a chair of standard height (43.2 cm) with no armrests. The number of completed sit-to-stand manoeuvres in 30 seconds is recorded. This test has been validated as a measure of lower-extremity strength against a one-repetition-maximum leg press ($r = 0.72$ to 0.78) in community-dwelling older adults.²⁷

Human Activity Profile⁹

The HAP consists of 94 activities, ranked in ascending order of difficulty according to the energy requirements (METs) of the task. Participants must choose among three options for each activity: (1) Still doing this activity; (2) Have stopped doing this activity; and (3) Never did this activity. Two scores are calculated from the HAP: a

Maximum Activity Score (MAS-HAP), which is the highest-numbered activity the person reports still doing; and an Adjusted Activity Score (AAS-HAP), calculated by subtracting the number of activities marked as "Have stopped doing this activity" that are listed below the MAS from the MAS-HAP score. For example, if "walking one mile" (activity #63) is the highest-numbered activity for which the participant has marked "Still doing this activity," the MAS-HAP score is 63; if the total number of activities below "walking one mile" that the participant has marked as "Have stopped doing this activity" is 3, the AAS-HAP score is 60. The HAP has been validated against accelerometer values (an objective measure of physical activity) over a 7-day period in people with ESRD ($r = 0.78$).²⁸

Procedures

One member of the research team (BP), a physiotherapist responsible for participant management, taught a diploma-trained physiotherapy assistant to administer the outcome measures. The 6MWT and TSS30 were conducted in the same quiet 30 m hallway, immediately prior to each participant's dialysis session. Test instructions and procedures for the 6MWT were standardized according to the accepted guidelines established by the American Thoracic Society.²⁴ The TSS30 preceded the 6MWT on both test occasions and served as a warm-up for the 6MWT. The tester walked slightly behind the participant during the 6MWT. Participants started at the instruction "Go" and stopped on the tester's command.

Statistical Methods

Participants' demographic and clinical information were summarized using descriptive statistics. Relative test-retest reliability was assessed for each outcome measure with the $ICC_{2,1}$,²⁹ using the information from two-way analysis of variance (ANOVA) tests. Confidence intervals (at the 95% level) around the $ICC_{2,1}$ were calculated using the method described by Streiner and Norman (2003).¹² A 95% CI indicates that there is a 2.5% chance that the true ICC will fall below the lower limit of the confidence interval and a 2.5% chance that the true ICC will fall above the upper limit of the confidence interval.¹² An $ICC_{2,1}$ greater than 0.9 was considered "excellent," values between 0.8 and 0.9 were considered "good," and those below 0.8 were considered to be of questionable clinical value.³⁰ Absolute reliability for each outcome measure was determined by calculating the SEM.¹³ The SEM, a reliability index that indicates the extent to which a score varies on repeated measurements,¹⁴ is calculated as follows: $SEM = SD\sqrt{1 - ICC}$. An MDC at the 95% level of confidence was calculated for all outcome measures using the SEM values, as follows: $MDC_{95} = SEM \times \sqrt{2} \times 1.96$.¹⁴ A statistical software

Table 1 Descriptive Characteristics of the Participants

	Men (<i>n</i> = 14)	Women (<i>n</i> = 11)	All Participants (<i>n</i> = 25)
Age (years) mean (SD)	66.3 (16.5)	68.5 (11.2)	67.2 (14.2)
Body mass (kg) mean (SD)	80.3 (15.5)	69.8 (24.0)	75.7 (20.0)
Other chronic diseases	11	9	20
Time on haemodialysis (years) mean (SD)	3.3 (3.0)	3.4 (1.7)	3.3 (2.5)

Table 2 Scores (mean, SD), Relative Reliability (ICC_{2,1}), Absolute Reliability (SEM), and Minimal Detectable Change (MDC₉₅) of Physical Function and Activity Outcome Measures on Two Occasions in People with End-Stage Renal Disease

	6MWT (<i>m</i>)	TSS30 (<i>reps</i>)	HAP	
			MAS	AAS
Trial 1 (mean, SD)	370 (105)	8.7 (3.5)	64 (11)	51 (14)
Trial 2 (mean, SD)	389* (107)	9.7* (3.8)	64 (11)	49 (14)
ICC _{2,1} (95% CI)	0.93 (0.82–0.97)	0.93 (0.58–0.98)	0.76 (0.53–0.89)	0.92 (0.83–0.97)
SEM	28	0.9	5.5	4.1
MDC ₉₅	77	2.6	15.1	11.4
Variance components				
Subjects	10,552.00	12.85	94.60	197.85
Occasions	135.56	0.44	0	1074
Error	715	0.50	30.30	14.70

* Significantly greater than for Trial 1, 6MWT: $p = 0.025$; TSS30: $p < 0.001$

AAS = adjusted activity score; HAP = Human Activity Profile; MAS = maximum activity score; 6MWT = 6-minute walk test; TSS30 = 30-second timed-sit-to-stand test; CI = confidence interval; ICC = intraclass correlation coefficient; SEM = standard error of measurement; reps = repetitions

package (SigmaStat version 2.03, SPSS Inc. Chicago, IL) was used for all data analyses. The Type I error level was set at 0.05.

RESULTS

A convenience sample of 25 adults with ESRD (14 male, 11 female) was recruited. There were no dropouts; data are therefore presented for all 25 participants. All participants completed the tests without incident. All participants were able to ambulate independently; six required a gait aid such as a walker. Demographic and clinical information of the participants is summarized in Table 1.

The participants' dialysis schedules remained unchanged during the study period, which ensured that the tests were performed at the same time on both occasions. The mean MAS-HAP scores were identical between test sessions, suggesting that the participants did not change in terms of physical function between tests. The mean AAS-HAP score changed from 51 to 49 on the second trial, a non-significant difference. Therefore, the entire sample of 25 participants was included in the analysis of reliability.

Total distance covered for the 6MWT, number of repetitions completed for TSS30, and MAS-HAP and AAS-HAP scores on both test occasions are presented in

Table 2. There was a significant increase from trial 1 to trial 2 ($p = 0.025$) in the distance walked for the 6MWT and in the number of sit-to-stand repetitions ($p < 0.001$) in the TSS30. The difference in mean scores on repeated testing for the AAS-HAP was not statistically significant. The mean score of the MAS-HAP did not change.

The results of the relative and absolute test-retest reliability analyses are also presented in Table 2. Relative reliability for the 6MWT, TSS30, and AAS-HAP was excellent (ICC_{2,1} values >0.90), while reliability for the MAS-HAP (ICC_{2,1} = 0.76) was of questionable clinical value.³⁰ The confidence intervals for the relative reliability of the outcome measures are presented in Table 2.

DISCUSSION

The purpose of this study was to determine relative and absolute reliability of some commonly used physical function and activity outcome measures in people with ESRD, in order to assist physical therapists in choosing appropriate measures to assess treatment programs. The main results of this study support the use of the 6MWT, the TSS30, and the AAS-HAP to differentiate between individuals with ESRD who are stable on haemodialysis; however, with a relative reliability of less than 0.8, the MAS-HAP may be better suited for research with large sample sizes, for the following two reasons. First,

research will draw conclusions from a mean score averaged across many individuals, and the sample size will serve to reduce the error of measurement in comparison to group differences. Second, decisions about research findings are not typically made on the basis of a single study; rather, they are usually drawn from a series of repeated studies.¹² The absolute reliability results for all outcome measures examined in the study are indicative of significant within-participant variability, suggesting that there is a wide range within which a truly unchanged participant's score will fall on repeated testing.¹⁴

The 6MWT results support the findings of earlier research by Holub et al.,²² who reported an ICC_{2,1} of 0.96 in a small sample of participants ($n = 19$) stable on haemodialysis. Similar reliability values (ICC_{2,1} between 0.81 and 0.96) have been reported for the 6MWT in healthy seniors,¹⁵ people with advanced heart failure (left ventricular ejection fraction <30%),³¹ and those awaiting heart transplantation.³²

The change in the mean distance walked between trials of the 6MWT was approximately 5%. For the TSS30, the change in the mean number of repetitions was approximately 11%. The difference in observed scores between trials for the 6MWT and TSS30 suggests that at least two trials are needed to achieve a stable estimate of baseline performance in people with ESRD. Since we performed only two tests, we are unable to determine whether a further change in scores would occur on a third trial.

While our tests were conducted at the same time of day for each participant, we cannot exclude a learning effect, changes in disease status, or the variability in daily function associated with ESRD as the reason for the changes observed on the second trial. Similar increases between 6MWT trials, ranging from 5% to 33%, have been reported in people with fibromyalgia, heart disease, and pulmonary disorders and in healthy adults.³³ Increments in 6MWT distance up to the third trial suggest that a minimum of three trials may be required for a stable performance in healthy adults.³³ However, in populations with fibromyalgia²¹ and with chronic heart and lung disease,³⁴ stable estimates of scores were obtained after only two trials.

Our results, indicating an increment of scores between trials, differ from those of Holub et al.,²² who reported no significant differences in scores across three 6MWT trials. This lack of change could be attributed to the physical differences between participants in the two studies. The 6MWT distance for Holub et al.'s participants (268 ± 104 m) was considerably shorter than that observed for the participants in our study (370 ± 105 m); in addition, their participants required contact-guard assistance for ambulation (light tactile support), while participants in the current study were independent ambulators, which further suggests differences in physical function between the two study samples.

The TSS30 scores in our study are within the range of values noted in interventional studies of people with ESRD.^{4,7} Of interest is that our participants' mean scores are in the 10th percentile of established normative values of the 6MWT and TSS30 for community-dwelling residents aged between 75 and 85 years and between 65 and 75 years, respectively.³⁵ This finding confirms several earlier reports of functional deficits in the ESRD population.^{4,36,37}

The developers of the HAP have suggested that the AAS-HAP is a stable estimate, whereas the MAS-HAP may provide unrealistically high estimates of physical activity.³⁸ Previous reports of the HAP in people stable on dialysis have shown scores similar to those of our participants.^{10,28} In a slightly younger population (mean age 51 years), scores for the MAS-HAP and AAS-HAP were 70.1 and 55.3 respectively,³⁶ and a drop in these scores was noted over a period of 1 month. Of interest is that the mean AAS-HAP score for participants in our study (51) was lower than the score (63) reported by Brouwer et al. for community-dwelling seniors who were reported to have curtailed physical activities due to fear of falling.³⁹

The relative reliability results for the MAS-HAP are suggestive of increased error variance on repeat testing. This could be a characteristic of our study population, as excellent relative reliability (ICC_{3,1} between 0.96 and 0.97) for the MAS-HAP has been reported among people 50 years or older with arthritis who had "pain."⁴⁰ The shorter test-retest interval in that population (2–7 days) may have facilitated recall on the MAS-HAP;⁴⁰ our test-retest interval was 7 days.

The absolute reliability of the outcome measures assists in estimating the precision of the scores on repeated testing. The SEM and MDC₉₅ have clinical utility because they are expressed in the same units as the original measure. For example, one SEM was 28 m for the 6MWT, 0.9 repetitions for the TSS30, 5.5 on the MAS-HAP, and 4.1 on the AAS-HAP. Thus, for an individual with scores of 350 m on the 6MWT, 9.0 reps on the TSS-30, 50 on the MAS-HAP, and 45 on the AAS-HAP, 68% of the time his or her true scores will lie between 322 and 378 m on the 6MWT, between 8.1 and 9.9 reps on the TSS-30, between 44.5 and 55.5 on the MAS-HAP, and between 41.4 and 49.1 on the AAS-HAP.¹⁴ There is no definition of "adequate" absolute reliability. The error values likely reflect day-to-day variability of physical function in people with ESRD that affect the precision of the scores. For example, Thomas-Hawkins has reported variations in physical function on a day-to-day basis with the use of the Inventory of Functional Status for Dialysis Patients.⁴¹

This is the first study to report an MDC₉₅ for the 6MWT (77 m) and the TSS30 (2.6 reps) for people with ESRD stable on haemodialysis. The MDC₉₅ defines the random fluctuation in scores of a truly stable participant;

clinicians can be confident, 95% of the time, that true change has occurred on repeat testing when a change in the score is greater than the MDC₉₅ value. Thus, if an individual walked 350 m on the 6MWT, our MDC₉₅ value suggests that a score on repeat testing of between 273 and 427 m would indicate a truly unchanged performance, 95% of the time. In comparison with our value of 77 m, using data from Fulk et al.²⁰ we calculated a 6MWT MDC₉₅ of 64.3 m in participants with stroke who had a locomotion score of 5 or higher on the Functional Independence Measure.

CONCLUSIONS

We have shown that some commonly used physical function and activity measures (6MWT, TSS30, and AAS-HAP) have excellent mean relative reliability and are useful in distinguishing among people with ESRD who are stable on haemodialysis. These tests are thus appropriate for use in day-to-day clinical practice; however, a minimum of two trials may be required to obtain a stable estimate of performance. Our results also show that there is a large interval within which an individual's true score will lie with repeated testing, 95% of the time.

KEY MESSAGES

What Is Already Known on This Topic

Physical function is diminished in people with ESRD. Physiotherapists monitor physical function in this population to assess disease progression as well as the effect of intervention programs. Outcome measures used to assess physical performance and capacity include the 6MWT, TSS30, and HAP. Absolute and relative reliability of these measures have not been fully established in people with ESRD.

What This Study Adds

The present study provides information on absolute reliability of the 6MWT in people with ESRD and is the first study to give estimates of relative and absolute reliability for the TSS30 and the HAP. These measures provide acceptable relative reliability; however, the magnitude of the absolute reliability statistics suggests important within-participant variability on repeat testing in this population.

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