Original Investigation

Validity of the Incremental Shuttle Walk Test to Assess Exercise Safety Initiating Cardiac Rehabilitation in Low-Resource Countries

Short-title: ISWT validity in cardiac rehab

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ABSTRACT

Purpose: To evaluate the validity of the Incremental Shuttle Walk Test (ISWT) to inform risk stratification in cardiac rehabilitation.

Methods: This is a cross-sectional study at the major Cardiac Rehabilitation (CR) center in a middle-income country. Clinically-stable adult cardiac patients underwent an Incremental Shuttle Walk Test (ISWT) and a stress test (ST), wore a pedometer for 7 days and completed the *Godin-Shepherd Leisure-Time Physical Activity Questionnaire*. Metabolic equivalents of task (METs) achieved on the ISWT were calculated.

Results: 115 patients were evaluated. The mean distance on the ISWT was 372.70±128.52 meters (standard deviation; mean METs=5.03±0.62). The correlation of the ISWT distance with ST METs (7.57±2.57), steps/day (4556.71±3280.88) and self-reported exercise (13.08±15.19 was r_s=0.61 ($p<0.001$), r_s=0.37 ($p<0.001$), and r_s=0.20 ($p=0.031$), respectively. Distance on the ISWT accurately predicted METs from the ST (area under the received operation curve=0.774). The ability to walk ≥410 meters on the ISWT predicted, with a specificity of 81.5% and a sensitivity of 65.6%, a functional capacity of ≥7 METs on ST.

Conclusion: The ISWT is an alternative way to evaluate functional capacity and can contribute to the process of identifying patients at low-risk for a cardiac event during exercise at moderate-intensity.

Keywords:

coronary artery disease; cardiac rehabilitation; functional capacity; risk; exercise

Condensed abstract

The Incremental Shuttle Walk Test (ISWT) was tested as a risk stratification tool in cardiac rehabilitation. Results showed that patients who can walk 410 meters on the ISWT and have no other clinical contraindications to exercise, can be considered safe to initiate a program of moderate-intensity exercise in CR.

INTRODUCTION

Coronary artery disease (CAD) is among the leading burdens of disease worldwide,[1] contributing to 15.5% of mortality in 2015.[2] The effectiveness of cardiac rehabilitation (CR) for the secondary prevention of CAD is well established,[3,4] given the approximately 20% decreases in mortality, morbidity and re-hospitalization with participation.

While exercise, one of the central CR components[5], is extremely safe[6], patients are assessed prior to CR initiation to ascertain if (1) they have any contraindications to exercise, (2) determine the risk of a medical event during exercise, (3) develop the best-suited exercise program, and (4) inform development of an individualized exercise prescription.[7] Guidelines[8,9,10,11,12,13] for this assessment and risk stratification are based largely on the results of a graded, maximal exercise stress test (ST). For example, patients are considered at low-risk for an adverse event during exercise if they have an ejection fraction >50%, no complex arrhythmias or symptoms, and a functional capacity ≥7 metabolic equivalents of task (METs) on a ST[8,9].

While it is recommended patients undergo a maximal ST before CR to identify those at high risk of exercise-related complications,[14] in some cases (advanced age, significant comorbidity) maximal testing is not appropriate.[15,16,17,18] Moreover, STs may not often be available outside of major centres, require specialized technicians and physicians be present, and equipment to perform. These are major barriers in many settings, particularly in low and middle-income countries (e.g., Brazil). Thus, a recent consensus statement on CR delivery in low-resource settings recommends that where a ST is not possible for initial assessment, a walk test can be performed.[5] Even in the high-resource countries walk test is recommended for pre-program exercise testing in low-risk patients.[19,20]

The incremental shuttle walk test (ISWT)[21] is recognized as a simple to administer, cost-effective and well-tolerated test to evaluate functional capacity.[22,23] It has been widely-used and validated in diseased populations[24,25,26,27,28,29,30] – including cardiac patients.[23,31] This is a symptom-limited and submaximal assessment,[32] whereby the patient walks around a 10-m course and a gradual increase in speed is dictated by audio signals[30] and minimal equipment is needed. To our knowledge however, the utility of the ISWT for informing initial CR assessment has never been rigorously tested, particularly in low-resource settings where it could be particularly useful. Therefore, the aims of the current study were to test the validity of the ISWT for this purpose, and to establish the corresponding ISWT distance to denote ≥7 METs of functional capacity (or low risk), and hence contribute to decisions regarding risk stratification for CR initiation.

METHODS

Design and Procedure

For this cross-sectional, observational study, baseline data from a randomized controlled trial conducted in a low-resource setting was analyzed (protocol available elsewhere[33]; https://clinicaltrials.gov/show/ NCT 02575976). The purpose of the larger trial was to test the effects of comprehensive vs exercise only CR vs usual care on functional capacity. Ethics approval was obtained. Baseline data were collected between March 2015 and April 2017, at the Rehabilitation Center of Hospital das Clínicas of UFMG in Brazil. CAD patients were approached during the CR physician consult after hospital discharge. With CR referral from the physician and informed written consent from the patient, potentially-eligible patients were scheduled to come on-site to complete baseline assessments, including the ST and after the ISWT. Patients' medications were not suspended for these tests.

Participants were asked to complete a sociodemographic questionnaire to establish the generalizability of the sample, among other surveys. Clinical information was extracted from medical charts.

Participants

CAD patients (i.e., acute coronary syndrome +/- revascularization) referred to CR were eligible. The inclusion criteria included being >18 years old. Exclusion criteria were: (1) heart failure (i.e., ejection fraction less than 45%); (2), complex ventricular dysrhythmias, (3) any comorbid physical (e.g., advanced cancer, disabling stroke) or serious mental condition (e.g., advanced dementia, substance dependence) which would interfere with the ability to exercise[7]; and, (2) any visual or cognitive condition that rendered it difficult to understand the instructions to perform the walk test or to complete the questionnaires.

Measures

Participants were asked to self-report sociodemographic characteristics such as highest educational attainment, income, as well as marital and work status. A brief questionnaire assessing depressive symptoms was administered (Patient Health Questionnaire-9; scores

≥9 indicative of possible depression).[34] Clinical characteristics extracted from medical records included risk factors cardiac history, ST results and medications. Anthropometric measures, such as weight, height and waist circumference were evaluated (obesity was defined as body mass index ≥30kg/m^2 and central obesity as 80 cm or more for women and 94 cm or more for men).[7]

ISWT

In accordance with Singh et al.'s[21] ISWT protocol, participants walked up and down a 10-meter course delimited by two cones. Speed was controlled by audio signals through 12 stages, of one minute duration each, with gradual intensity increases. One practice walk with the first audio signal stage was done. All participants performed the test while wearing pulse oximeter (More Fitness®) and a heart rate (HR) monitor (Polar®) set to alert when HR went above the maximum HR achieved on the ST; these parameters were assessed every minute without interruption to the test. Blood pressure (Mobile stand Sphygmomanometer, Welch Allyn®, NY, USA) and perceived exertion (0 to 10 modified Borg scale)[35] were assessed before and immediately after the test.[36]

The test was timed, and the endpoint was the first of: (1) inability to maintain the speed related to the stage, (2) the attainment of the maximal HR achieved during the ST, or 10bpm below if the ST end-point was the presence of angina, or (3) cardiac symptoms (i.e., angina, dyspnoea) or adverse events. All tests were administered by the same trained physiotherapist. Only one test was performed, as it has been previously demonstrated in this population that ISWT is reproducible after just one practice walk,[37] and provides as good an estimate of exercise capacity as repeating the test.[38]

Several parameters were established from the test. The walked distance was calculated based on the number of shuttles performed,[21] the maximal HR achieved was recorded as well as the test time. In addition, two methods were used to calculate METs. First, the metabolic equations for walking published by ACSM based on linear regression equations were used.[9] Second, recently Buckley et al[39] demonstrated that the VO_2 of walking in cardiac patients responds not in a linear fashion as proposed by ACSM,[9] but as a curvilinear function of speed.

Other Functional / Exercise Assessments

The maximal ST was used to assess criterion validity. It was undertaken as part of the initial CR intake assessment in the Ergonometric Department of the hospital. The treadmill protocol applied was based on participant's clinical status, and included the Ramp (small increments), Bruce, Ellestad (more intense protocol), Modified Bruce, and Naughton (for older age or in the case of functional limitations)[40] protocols. For each test, blood pressure, HR and electrocardiography were continuously monitored. Patients were consistently instructed to avoid holding handrails and encouraged to work as hard as possible. The test end-point was the first of: (1) presence of symptoms (angina, dyspnoea, fatigue), or (2) the attainment of the HR max (i.e., 220 – age). As VO_2 was not measured directly, peak MET values from the ergometric software (specific equations to the treadmill protocol based on peak workload) were used.[40]

To assess construct validity, physical activity was assessed via pedometer (Ten Thousand Pace Checker SM-2000) and through the Godin-Shepherd Leisure-Time Exercise questionnaire.[41] With regard to the former, each participant received a pedometer and a pedometer log to record the number of steps undertaken each of 7 days.

Pedometers are shown to provide an accurate measure of energy expenditure.[42] An average was taken to represent mean steps / day. It is recommended cardiac patients accrue 7-8,000 steps / day.[43]

The Godin-Shepherd-Questionnaire[44] is a self-administered tool, which evaluates the frequency and intensity of physical activity performed for at least 15 minutes duration, over a week. The frequency indicated was multiplied by an intensity-specific coefficient, corresponding to the energy expenditure in METs of the given activity (vigorous=9, moderate=7 and light=3). The total score was calculated by summing the products of each intensity (for at least 15/minutes/week), as shown in the following formula: (9 × Vigorous-frequency) + (5 × Moderate-frequency) + (3 × Light-frequency)[44]. Total scores ≥24 were considered indicative of being sufficiently "active"[45] (i.e., corresponds to guideline recommendations of 150 mins of moderate-to-vigorous leisure-time physical activity weekly).[46]

Statistical Analysis

Analyses were performed using SPSS Version 24.0 (IBM, Somers, NY, USA). The normality of data distribution was assessed using the Shapiro-Wilk test. Descriptive analysis was used to characterize the sociodemographic and clinical characteristics of the sample.

The Spearman's rank correlation coefficient (r_s) was computed to evaluate the association between the ISWT parameters (walked distance, test time, HR and estimated METs using both formulas), and the other indicators of functional/exercise capacity to test validity, namely METs from the ST (criterion), number of steps / day measured by pedometer, and the Godin-Shepherd score. A $p<0.05$ was considered statistically

significant. The correlation was considered high with r_s greater than 0.75; moderate with r_s between 0.50-0.75; fair with r_s between 0.50-0.25; and low when r_s was < 0.25.[47]
A receiver operating characteristic (ROC) curve was plotted to evaluate the ISWT accuracy to predicted METs on ST (area under the curve) as well as in the establishment of the optimal cut-off point (considered as the highest sum of sensitivity and specificity [Youden's Index][48] with specificity > 80% for the ISWT walking distance), which would correspond to a functional capacity of ≥7 METs on the ST. Finally, the consistency of results across the different treadmill protocols (with more than 30 patients) were checked by area under the curve.

RESULTS

Of 132 eligible patients approached, 115 (87.1%) patients consented to participate. Their characteristics are presented in Table 1. Participants were taking the following medications: anti-platelets (n=81; 70.4%), acetylsalicylic acid (n=106, 92.2%), beta-blockers (n=100, 87.4%), statins (n=111, 96.5%), angiotensin-converting enzyme inhibitors (n=73, 63.5%), and angiotensin II receptor blockers (n=26, 22.6%).

The main reason for terminating the ISWT was that participants could not maintain the speed related to the stage (n=74, 64.3%). No cardiac symptoms or adverse events were observed during the ISWT. On the ST, the protocols mainly used were ramp (n=68; 58.6%) or Bruce (n=38; 32.8%). The reason the ST was terminated was most-often dyspnea (n=98, 85.2%). Six participants (5.21%) experienced angina during the ST. Functional / exercise capacity indicators are shown in Table 2. As expected, the maximal METs and HR achieved during the ST was higher than the ISWT. No participants achieved ≥7 METs on the ISWT (as calculated via both ACSM and Buckley), and 61

(53.04%) achieved ≥7 METs on the ST. Sixteen (14.7%) of 109 participants with valid pedometer data achieved ≥7500 steps/day.

Figure 1 displays the association of the ISWT distance and ST METs considering all protocols and Bruce and Ramp protocols separately. The associations between the ISWT and other functional / exercise capacity indicators are shown in Table 3. The association between the HR on the ISWT and on the ST was r_s =0.507 ($p<0.001$). Most associations with the ST were significant and moderate, and all were in a positive direction. Associations with steps / day and self-reported physical activity were generally significant and fair.

Figure 2 shows the ROC curve plotted to determine the optimal discriminatory accuracy of ISWT distance predicting ≥7 METs on the ST. The ability to walk more than 410.00 meters as cut-off point, predicted an estimated METs ≥7 on the ST with a specificity of 81.5% and a sensitivity of 65.6%. Moreover, a good performance (area under the curve) was found: 0.774 (95% confidence interval [CI]: 0.687-0.862) for distance walked. Considering Bruce and ramp protocols separately, area under the ROC curve for distance walked were 0.791 (95% confidence interval [CI]: 0.637-0.945) and 0.710 (95% confidence interval [CI]: 0.583-0.839), respectively.

DISCUSSION

Although the ISWT has been widely recommended for CR settings,[39,49] to our knowledge, this is the second study to evaluate the validity of the ISWT in the CR setting and its utility in stratifying CAD patients with regard to risk to initiate exercise,[38] and the first in a low-resource setting. Results provide evidence of the criterion validity of the ISWT in recently-hospitalized cardiac patients, and suggests it would be a useful, and low-resource test to use to inform decisions on whether it is safe for patients to initiate exercise and develop their exercise prescriptions, where the gold standard ST is not available or feasible.

Furthermore, the ability to walk more than 410 meters on the ISWT predicted, with a sensitivity of 65.6% and a specificity of 81.5%, a functional capacity of ≥7 METs on a ST, which is an important cut-point to stratify CAD patients as low risk to exercise at moderate intensity. The sensitivity is somewhat low. To avoid false-positives (i.e., considering someone as low risk when they are not), sensitivity was sacrificed at the expense of specificity when determining the best threshold (in addition to Youden's index). Nevertheless, in conjunction with assessment of other clinical factors by trained providers, the ISWT may be a safe, acceptable and low-cost means hence to contribute to risk stratification for CR initiation.

The moderate correlation (0.58) between ISWT distance and METs on ST supports the validity of the ISWT in CR. A strong correlation (0.85) was found between the duration of a symptom-limited test and ISWT distance in the only other study in the CR setting,[38] corroborating the validity of the ISWT in this setting is robust.

This study further supports the safety of the ISWT in CR, given the absence of adverse events during the test, as has been previously reported.[37] It is important to emphasize that the level of intensity on the ISWT was lower than during the ST, considering the maximal HR achieved, the % of the maximal HR predicted and the predicted METs. It is recommended[21,50] terminating the ISWT when 85% of the HR max predicted by age is achieved. Although in the present study we considered the % of the maximal HR achieved on the ST (in the presence of the CR physician), the % of the HR max predicted by age on the ISWT was under 85% of the HR max. This result also supports the use of the ISWT in informing initial assessment in the CR setting.

With both functional capacity tests, patients reached their fatigue limits in 6 to 12 minutes, which is a suitable length.[12,51] A duration of less than 6 minutes may not be adequate to establish a relationship between VO_2 and effort. In contrast, a test protocol lasting above 12 minutes may be terminated due to muscle fatigue or orthopedic factors, rather than cardiopulmonary ones.[51]

Consistent with the linear relationship between increments in walking speed and VO_2 observed by the ACSM[9] and questioned by Buckley et al,[39] we demonstrated that these two ways to estimate METs from an ISWT have a positive correlation with METs on a ST. Besides being an important predictor of functional capacity, it was shown[52] that METs calculated by different functional capacity equations were a simple and reliable measure to predict mortality in CAD.[17]

The instruments used to evaluate the level of physical activity were not reliable indicators of functional capacity, as reported previously,[17] given the low correlations, although positive and significant. Despite the accessibility of pedometers, one important consideration is inadequate reliability shown in previous studies.[53,54] One of the major issues is that many pedometers are unable to detect ambulation during slow walking, and in this case, they under-estimate the number of steps/day. Considering MET reached in ST, the score in Godin indicates the tendency of patients to over-report and over-estimate activity, as observed previously.[55]

Clinical & policy implications

While it is not being suggested that the ISWT should substitute the ST,[56] walking tests could be used as an alternative tool when STs are not feasible due to clinical, capacity/availability or economic reasons[22], as recommended by guidelines[57,58]. The ISWT can also be used to exercise prescription (target HR[59]) and assess individual's response to therapeutic interventions.[22] With regard to the former, given the ISWT is considered a sub-maximal assessment, and thus the ischemic threshold may not be determined,[32] the initial exercise prescription should be lower intensity when compared to the gold standard. With regard to the latter, the ISWT can be used to track CR effects on exercise capacity and establish outcomes.[60]

In some countries, the 6-minute walk test is used in CR programs to evaluate exercise capacity[28]. This has 2 limitations when compared to the ISWT. In the 6-minute test, while there is operator encouragement[61], the speed of walking is determined by the patient (who would have varying degrees of motivation). Although standardized phrases are used to motivate patients consistently[61], the degree of encouragement of the operator in stating these phrases may influence the distance walked. The external pacing of the ISWT on the other hand reduces this potential bias.[61] Second, the shorter length of the corridor required to undertake the ISWT would also be an advantage for CR programs where space is limited.

Study Limitations

The findings presented in this study should be interpreted with caution. First, the ISWT was administrated by the same researcher using the standard protocol,[21] but the ST was administered by different professionals, using different protocols. However, it improves the external validity because, at least in Brazil, this reflects real-life practice. Moreover, results were similar at least for the Bruce and Ramp protocols. Second, the researcher was not blind to the results of the ST, because the HR max of the ST was used to calculate the HR max in the ISWT. Third, the order of the ISWT and ST was not randomized. Finally, generalizability is limited for several reasons: (1) the study was conducted at a single center, (2) it was conducted in only one middle-income country (replication is recommended), and (3) the exclusion criteria omitted participants who could be at higher-risk (including those with low ejection fractions). Future research is warranted to explore the safety of the ISWT in informing pre-CR assessment in all types of patients referred to CR (or perhaps should be used only for patients for which there are no known clinical considerations which may put them at higher risk).

CONCLUSION

The ISWT is a viable adjunct to functional capacity evaluation in CAD patients where a ST is infeasible or impractical. The validity of the ISWT in assessing METs in relation to gold standard has been corroborated, which supports its' utility in informing risk stratification for the initiation of moderate-intensity exercise in CR.

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FIGURE 1 LEGEND

Figure 1. Association between Incremental Shuttle Walk Test (ISWT) distance walked and Metabolic equivalents of Task (MET) at stress test (ST). (A) All ST protocols, n=115, rho= 0.584, p<0.001. (B) Bruce protocol, n= 38, rho = 0.569, p<0.01. (C) Ramp protocol, n= 68, rho = 0.577, p<0.01. Regression line (continuous line) and 95% confidence intervals (dotted lines)

FIGURE 2 LEGEND

Figure 2. Receiver operating characteristic (ROC) curve of the accuracy of Incremental Shuttle Walk Test (ISWT) distance walked to stratify risk considering the cut-off of 7 Metabolic equivalents of Task (MET), by computation method.

ACSM: American College of Sports Medicine

Table 1. Sociodemographic and clinical characteristics of participants (N=115).

Characteristic	**mean ± SD / n (%)**
Sociodemographic	
Age, years	59.48±9.44
Sex (% Male)	82 (71.3%)
Highest Educational Attainment	
Initiated High School	82 (71.3%)
Marital status	
Single	15 (13.0%)
Married	74 (64.4%)
Widowed or divorced	26 (22.6%)
Work Status	
Employed	46 (40.0%)
Retired	51 (44.3%)
Unemployed	18 (15.7%)
Monthly Family Income	
Income < $282.22 [a]	30 (26.0%)
Income between $564.45 and $846.66	70 (60.9%)
Income over $1128.88	15 (13.1%)
Clinical	
First cardiac event (% yes)	28 (24.9%)
No previous CR participation	111 (96.5%)
CR Indication (% yes)	
Myocardial Infarction	107 (93%)

Percutaneous coronary Intervention /Stent	68 (59.1%)
Coronary Artery Bypass graft surgery	29 (25.2%)
Angina	69 (60%)
Risk factors	
Hypertension	95 (82.6%)
Diabetes Mellitus- type 1	8 (7.0%)
Diabetes Mellitus -type 2	22 (19.1%)
Dyslipidemia	79 (68.7%)
Cholesterol, mg/dl	155.67±46.95
LDL, mg/dl	83.13±27.96
HDL, mg/dl	40.68±10.11
Triglycerides	148.60±85.61
Obesity	35 (30.4%)
Central obesity	50 (43.5%)
Depression[b]	20 (17.4%)
Smoking Status	
Never smoked	39 (33.9%)
Former smoker	67 (58.3%)
Currently smoke	9 (7.8%)

SD- standard deviation. BMI- Body Mass Index, LDL- Low-Density Lipoprotein, HDL- High-Density Lipoprotein, CR- Cardiac Rehabilitation.

[a] this is the minimum salary/ month in Brazil; Note 1 US$ = 3.32 Brazilian Reais.

[b] from Patient Health Questionnaire-9

Table 2. Indicators of Functional / Exercise Capacity

Indicators	**Mean ± SD (N = 115)**	**Range (median)**
ISWT		
Distance (metres)	370.27±120.85	70.00-720.00 (375.00)
HR (bpm)	102.84±17.49	56.00-159.00 (101.50)
% HR max predicted [a]	64.09±9.95	36.00-99.00 (63.26)
Test time (MM:SS)	06:33±01:40	0:01:11-0:09:54 (06:58)
METs (by ACSM)	5.03±0.68	3.40-6.60 (5.00)
METs (by Buckley *et al.)*	4.38±0.90	2.19-6.59 (4.34)
Stress Test		
METs	7.57±2.51	1.68-13.13 (7.32)
HR (bpm)	121.41±21.96	72.00-187.00 (119.00)
% HR max predicted [a]	75.58±12.51	50.00-121.00 (74.44)
Test Time (MM:SS)	07:06±02:34	00:43-13:26 (06:58)
Physical activity		
Pedometer (steps / day)	4556.78±3280.88	171.28-21360.00 (3867.14)
Godin-Shepherd[b]	13.08±15.19	0-85.00 (9.50)

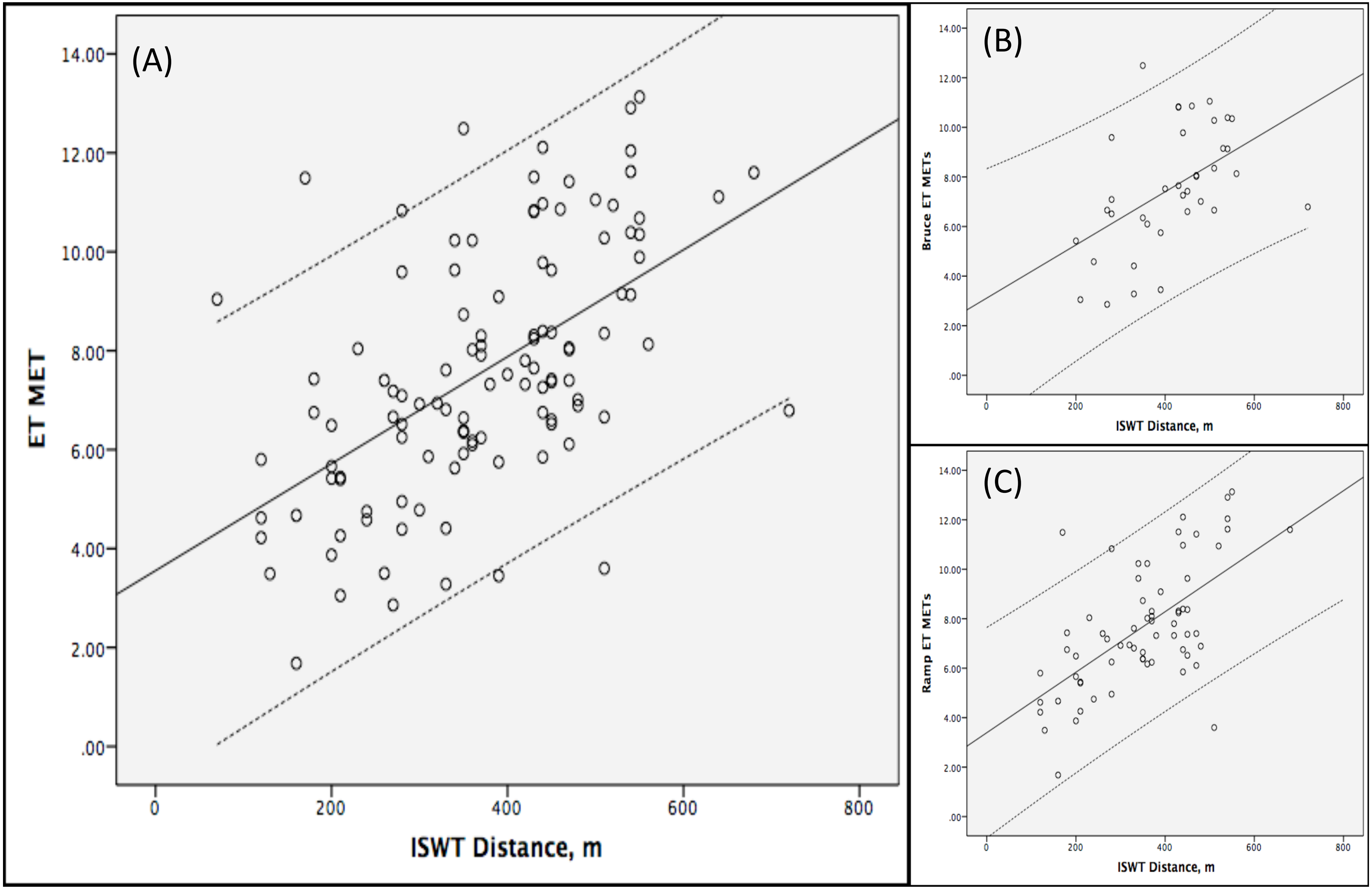
SD- standard deviation, ISWT- Incremental Shuttle Walk Test, HR- heart rate, max= maximum, bpm- beats per minute, MET- Metabolic Equivalent of Task, ACSM- American College of Sports Medicine, ST – stress test, MM:SS- minutes:seconds

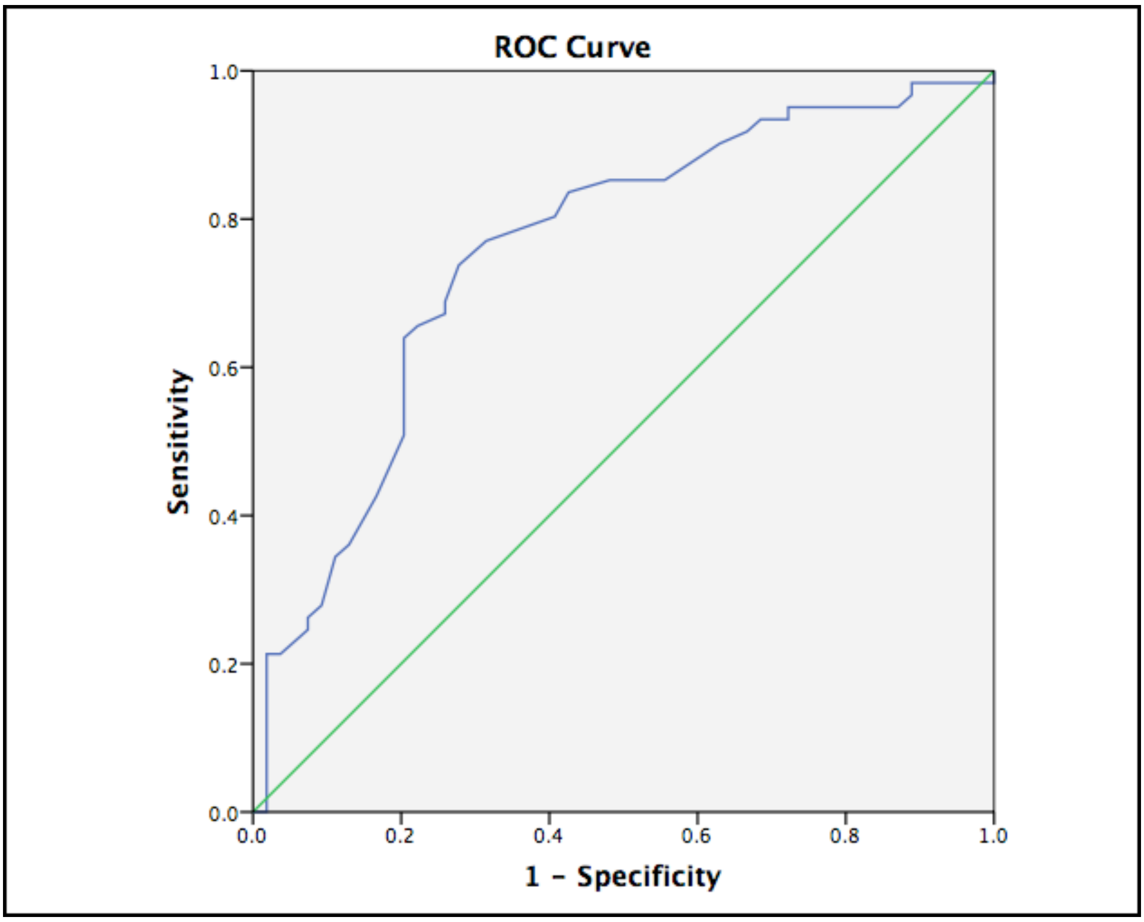
[a]220-age. [b]total scores ≥24 reflect sufficient activity per week (i.e, 150 mins moderate to vigorous intensity.

Table 3. Correlations between ISWT and Functional / Exercise Capacity Indicators

Spearman's rho p	ISWT Distance	ISWT MET by ACSM	ISWT MET by Buckley	ISWT HR
Criterion Validity				
ST MET	0.584 p<0.001	0.615 p<0.001	0.617 p<0.001	0.287 p=0.002
ST HR	0.577 p<0.001	0.552 p<0.001	0.555 p<0.001	0.507 P<0.001
Construct Validity				
Pedometer	0.354 p<0.001	0.374 p<0.001	0.370 p<0.001	0.195 p=0.045
Godin-Shepherd	0.215 p=0.021	0.202 p=0.031	0.202 p=0.030	0.059 p=0.539

MET- Metabolic equivalents of Task, ISWT- Incremental Shuttle Walk Test, ACSM- American College of Sports Medicine, ST- Stress Test, HR – heart rate


(A)
ET MET
ISWT Distance, m
14.00
12.00
10.00
8.00
6.00
4.00
2.00
.00
0
200
400
600
800
(B)
Bruce ET METs
ISWT Distance, m
(C)
Ramp ET METs
ISWT Distance, m


ROC Curve
Sensitivity
1 - Specificity
0.0
0.2
0.4
0.6
0.8
1.0