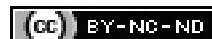


Test-retest Reliability and Minimum Detectable Change of 2-Minute Walk Test among Individuals with Knee Osteoarthritis

SHEFALLY CHAUDHARY¹, AMMAR SUHAIL²

ABSTRACT

Introduction: The 2-Minute Walk Test (2MWT) is a simple, practical, and less time consuming test. Patients do not get fatigued while performing this test as a part of routine physical examination. 2MWT shows an excellent correlation with other walk tests and can be used as an alternative test in patients with multiple comorbidities. The reliability of a test is a must for its recommendation to be used in clinics as well as research. Measurement properties have been reported in different populations for 2MWT. However, no data exist for 2MWT in patients with Knee Osteoarthritis (KOA).

Aim: To establish the test-retest reliability and Minimal Detectable Change (MDC) scores for the 2MWT in patients with bilateral KOA.

Materials and Methods: A prospective test-retest research study designed to assess the reliability of 2MWT. Eighty-two patients with KOA (27 males and 55 females) were included in the study. Health status was assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The Numeric Pain Rating Scale (NPRS) and WOMAC were assessed on two consecutive days. Participants performed 2MWT on two different

occasions with 48 hours difference in between. Both sessions were conducted for 45 minutes each on a 30 meter walking pathway. Data was analysed using Statistical Package for the Social Sciences (SPSS) version 20.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results: 2MWT showed an excellent test-retest reliability. Intraclass Correlation Coefficient (ICC) for 2MWT were 0.98. Test-retest reliability assessed by two trials of 2MWT showed 1st trial mean \pm SD of 154.33 \pm 19.59 m and 2nd trial mean \pm SD of 156.69 \pm 19.68 m. Mean difference \pm SD between both trials was 2.36 \pm 2.74, which was statistically significant ($p < 0.001$). The Standard Error of Measurement (SEM) and Minimal Detectable Change at 95% confidence level (MDC95) for 2MWT were 2.76 and 5.52 meters, respectively.

Conclusion: The study recommends that 2MWT can be used as a test for assessing walking capacity among patients with KOA. A change of more than 5.52 meters can be considered as change-free of error. It can be used as an alternative to 6MWT in patients with KOA who cannot tolerate a higher duration/intensity walk test.

Keywords: Outcome measure, Performance-based measures, Walking capacity

INTRODUCTION

Osteoarthritis (OA) is the most ubiquitous form of arthritis [1,2]. Comparatively, knee is 41% more affected than other joints from OA [3]. The prevalence of KOA is reported as 28.7% among the Indian population [1]. Hip and KOA are significant contributors to disease burden and increased healthcare costs worldwide [2,4]. KOA is associated with pain and can result in difficulty in daily functional tasks such as stair climbing, walking, getting in and out of a chair [5,6]. Balance and gait impairments are frequent findings in participants with KOA [7-9].

Gait dysfunctions among KOA patients is associated with an increased risk of disease specific mortality [10]. These dysfunctions can be measured using either patient-reported or performance-based outcome measures. Performance-based measures are analyser-observed measures of tasks that are assessed through timing, counting, or distance methods [11,12]. These outcome measures assess what individuals can do instead of what they perceive as they can do [13]. These tests assess physical functions such as walking speed and capacity [11].

Walk tests are performance-based measures that measure individuals walking capacity. A range of walk tests are used in KOA individuals to estimate the walking capability, such as the 6MWT, 5 m (16.4 ft), multi-paced test, 13 m (42.7 ft) self-paced test. These tests are usually time-based (6MWT or 2MWT) or distance-based (one-mile walk test) [14]. A 6MWT and 2MWT are modifications of the 12MWT. High correlations have been reported for 12MWT, 6MWT, and 2MWT in different populations [14]. It is suggestive that some individuals are unable to walk for six minutes because of pain, muscle weakness, and

low endurance [15]. Therefore, 2MWT can be a better practical and tolerable test for KOA affected individuals.

2MWT test's measurement properties have been studied in various populations [12,15-19]. To the best of our knowledge, the properties of 2MWT have not been tested in KOA (bilateral) individuals. Therefore, the present study aimed at assessing the test-retest reliability of 2MWT among patients with bilateral KOA. It also aimed to analyse the minimum detectable change of 2MWT.

MATERIALS AND METHODS

The study was a prospective test-retest research designed to assess the reliability of 2MWT. Participants were recruited from the Physiotherapy clinic, Department of Physiotherapy, Uni Hospital, Lovely Professional University and Vishwakarma Hospital, Phagwara, Punjab, India. The study was conducted from January 2017 to April 2017. The study was approved by the project approval committee of Lovely Professional University.

Sample size calculation: Sample size was estimated using G power version 3.1. The minimum sample size of included individuals to justify enough power was set at 80. A power analysis determined that a minimum of 78 participants were required to establish a minimally acceptable reliability coefficient of 0.85 with $\alpha = 0.05$.

Inclusion criteria: Eighty-two participants were recruited using purposive sampling in the study. They were included in the study if they: (1) were aged between 45 years or above; (2) had a diagnosis of bilateral KOA (Kellgren-Lawrence (KL) rating > 1); (3) had knee pain of ≥ 3 months; (4) NPRS score ≥ 3 ; (5) was able to walk with or without an assistive device.

Exclusion criteria: Participants were excluded if they had a history of a major surgical operation of the lower limb, any previous history of traumatic injury of lower limbs, and surgical history of the spine. Patients who were diagnosed with heart and lung diseases were also excluded from the study.

Procedure

The baseline assessment was done on the first day of the participant's visit. Health status was assessed using WOMAC [20, 21]. The NPRS and WOMAC were assessed on two consecutive days. On the first visit, their necessary information along with pain and health status were assessed. A familiarisation session of 2MWT was conducted before the initial testing. There were two trials of 2MWT to assess the test-retest reliability, with 48 hours interval. The trial sessions lasted for approximately 45 minutes. First author did all the data collection procedures. During the testing procedure, an assistant was present to prevent participants from falling. The scores obtained in the 2MWT were used to ascertain test-retest reliability and MDC. A 2MWT was performed as described by Pin TW [14].

The walk test was performed on a 30 meter walking pathway. The turnaround points were marked with a cone. Participants were instructed to walk at a normal pace and not to run or jog. If the participants felt it necessary to stop at any point in time, they could stop and resume back walking when they felt comfortable. When the time was up, the subject was asked to stop, and the total distance was recorded.

STATISTICAL ANALYSIS

Data was analysed using SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA). Shapiro-Wilk test was used to test the normality of the data. The p-values of 0.05 or less were considered significant. The calculation of test-retest reliability for 2MWT was done using the ICC, and the SEM with a 95% confidence interval was determined to confirm the accurateness of the measurement method. The following formulae were used to calculate the SEM and MDC95.

$$\text{SEM} = \text{SD baseline} \times \sqrt{1 - \text{ICC}}$$

$$\text{MDC } 95\% = 1.96 \times \sqrt{2} \times \text{SEM}$$

RESULTS

The demographic characteristics of the sample are highlighted in [Table/Fig-1]. The mean (SD) age of the participants was 60.42 (6.6). Twenty-seven participants were male, and 55 were females. The participant's NPRS and functional status are shown in [Table/Fig-2], comparing both measurements. The correlation between Body Mass Index (BMI) and 2MWT [Table/Fig-3] ($r=0.017$), to see if the BMI affected the distance walked, was not significant with a p-value of 0.87.

Characteristics	Mean±SD
Age (years)	60.43±6.65
Weight (Kg)	71.55±11.57
Height (m)	1.62±0.082
BMI (Kg/m ²)	27.27±3.33
Gender (Male: Female)	27: 55

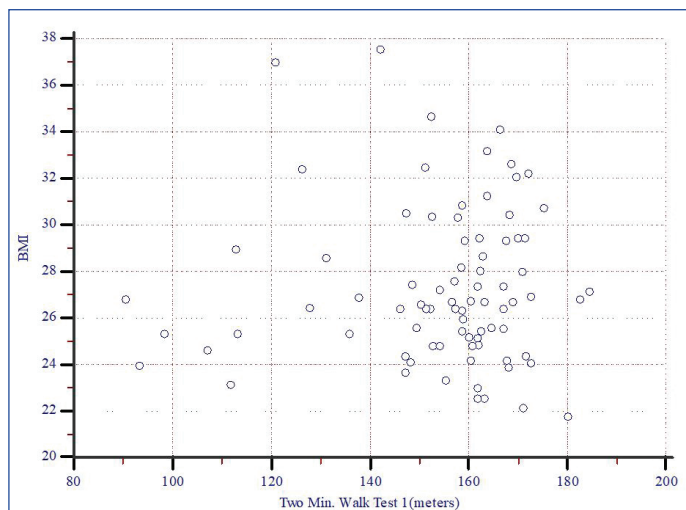
[Table/Fig-1]: Baseline characteristics of the participants.

Kg: Kilogram; m: meter; SD: Standard deviation

Variable	1 st day mean (SD)	2 nd day mean (SD)	Wilcoxon (p)
Numeric pain rating scale (left)	5.5 (1.3)	5.4 (1.6)	0.56
Numeric pain rating scale (right)	4.6 (1.4)	4.6 (1.5)	0.73
WOMAC	42.3 (6.1)	43.1 (13.9)	0.18

[Table/Fig-2]: Pain and functional status of the participants.

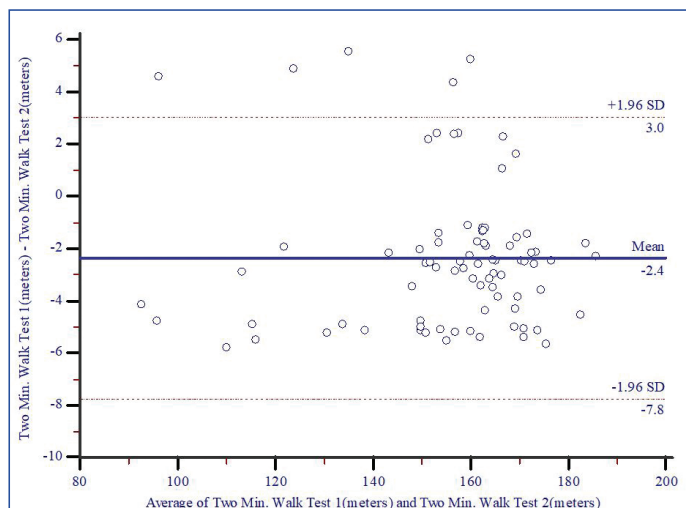
WOMAC: Western Ontario and McMaster Universities osteoarthritis index; SD: Standard deviation



[Table/Fig-3]: Scatterplot showing relationship between BMI (kg/m²) and 2MWT distance.

Reliability of Measure

The test-retest reliability of 2MWT was measured using ICC (2,1). The ICC, MDC, and SEM are presented in [Table/Fig-4]. There was a statistical difference between the first and second trial of 2MWT, participants walked 2.36 meters (m) longer in the second trial of 2MWT ($p<0.001$). The 2MWT showed excellent reliability, ICC was 0.98 [Table/Fig-5].



[Table/Fig-4]: Bland Altman plot of agreement between test-retest scores of 2MWT.

	1 st trial mean±SD	2 nd trial mean±SD	Difference mean±SD	ICC (95% CI)	SEM	MDC95
2MWT (meters)	154.33±19.59	156.69±19.68	2.36±2.74*	0.98 (0.9924-0.9968)	2.76	5.52

[Table/Fig-5]: Test-retest reliability assessed by two trials of 2MWT.

* $p<0.001$; 2MWT: 2-minute walk test; ICC: Intraclass correlation coefficient; CI: Confidence interval; SEM: Standard error of measurement with a 95% confidence interval; MDC95: Minimal detectable change at the 95% confidence level; SD: Standard deviation

Limits of Agreement (LOA) Plots

The Bland Altman plot [Table/Fig-4] showed a high level of agreement between the two measurements. There were only five data points outside the +1.96 SD. The mean difference between the measurements was 2.4.

DISCUSSION

The 2MWT showed excellent test-retest reliability in individuals with bilateral KOA. Individuals walked more during the 2nd trial though there was no change in pain or WOMAC score between the two trials. This might be due to learning effect as individuals learned how to do the test.

Reliability of an outcome measure is critical as the information provided should be consistent and responsive to changes in a patient's condition. Reliability is reflected in terms of consistency and repeatability when administered properly under similar circumstances [22]. Clinically, reliability is an essential construct as it helps clinicians correctly interpret the results of a test. In the present study, the test-retest reliability of 2MWT was assessed using the ICC. Test-retest reliability measures test consistency; if the same test is given to the same individuals at different times, it should provide identical scores.

Different studies have evaluated the reliability of 2MWT in different disease populations [12,17-19,22-29]. However, no study has reported test-retest reliability of 2MWT in KOA patients. An excellent test-retest reliability with an ICC of 0.98 (0.9924 to 0.9968) was observed. The ICC used in the study was a two-way random effect, absolute agreement, single rater/measurement usually represented as ICC (2,1) [30]. The ICC values' interpretation must depend on the type of ICC used and the measured confidence intervals. A ≥ 0.9 (ICC) indicates excellent test-retest reliability [30].

In literature, for the 2MWT, ICCs between 0.83 to 0.99 have been reported in distinct populations [12,16,25,26]. The present study results agree with the previous studies evaluating test-retest reliability of 2MWT among a diverse population. Resnik L and Borgia M, evaluated test-retest reliability among participants with lower-limb amputations, and they reported an ICC of 0.83 (95% CI) [25]. Leung ASY et al., witnessed comparable ICC values of >0.99 were reported in Chronic Obstructive Pulmonary Disease (COPD) Participants [26]. Yuksel E et al., reported ICC values of 0.96 and 0.97 among total knee replacement and hip replacement patients respectively. In this study, the value of ICC among bilateral KOA is in accordance with the reported values by Yuksel E et al., [12,16].

The ICC values must be used along with the SEM and MDC as it alone is of little clinical importance. The values obtained from tests should be useful for clinicians; hence SEM and MDC must also be calculated for any tests to be of value in practice [16]. MDC is the bare minimum change in the scores of a tool that must occur in an individual to ensure that the change in score is not merely attributable to measurement error [31]. MDC is a statistical concept and is measured using SEM values. MDC calculation requires that participants be measured at two points with minimal difference in between those measurements. Present study measured 2MWT on two different occasions with 48 hours in between the measurements.

In literature, the MDC95 values for 2MWT range from 12.2 m to 34.3 m [14]. The highest MDC95 value has been reported as 34.3 m in patients with lower extremity amputation by Resnik L et al., [25]. The lowest value was reported as 12.2 m for older adults [29]. In the present study, MDC95 for 2MWT was 5.52 m. Compared to other studies, the low MDC95 value is due to specificity associated with the present study population; performance-based measure results are dependent on the population studied. The data showed that individuals walked more on the second day ($p < 0.001$). This could be due to familiarisation with the test as there was no difference in pain score during the study duration.

Limitation(s)

The limitation of the study is that only one aspect of reliability was assessed due to the participants' availability. The population included in the study was only from two outpatient clinics, thus limiting the generalisability of the findings. The strength of the study is using a standardised protocol of 2MWT. In the literature, different methods of performing the test were described; we used the recommended description of performing the 2MWT as described by Pin TW [14].

CONCLUSION(S)

The study concluded that 2MWT is a safe and easy test for measuring walking ability among patients with KOA. 2MWT has excellent test-retest reliability for individuals with bilateral KOA. More than 5.52 m

changes can be confidently considered actual difference in the patient's ability to perform the task. Therefore, it is concluded that for functional evaluation in KOA, 2MWT is an excellent alternative to other walk tests such as 6MWT and 12MWT.

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