Clinically Assessed Walking Capacity Versus Real-World Walking Performance in People with Multiple Sclerosis

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CME/CNE Information

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Learning Objectives:

1) Differentiate between measurement tools for clinical walking capacity and for real-world performance.
2) Describe discrepancies between performance on a walking capacity test and real-world performance, and how these discrepancies vary between patients with high versus low walking capacity.

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Background: **Ecological validity is an important psychometric property when assessing function. How a person with multiple sclerosis (MS) performs in clinical settings and in natural environments can be quite different. Walking is the most frequently assessed and recommended way to maintain health in a progressive disease such as MS. The objective was to estimate the extent to which clinical tests of walking capacity differ from real-world walking performance in people with MS.**

Methods: **Ninety-eight women and 27 men with MS were assessed using the 6-Minute Walk Test (6MWT) and wore an accelerometer for 7 consecutive days. Mean number of steps, mean number of steps at a brisk cadence or faster, and cumulative time per week spent walking at a brisk cadence or faster were regressed on 6MWT categories using quantile (median) regression. Contiguous steps were grouped into bouts of less than 5 minutes and 5 minutes or longer, and number of bouts 5 minutes or longer was regressed on 6MWT categories using a zero-inflated Poisson model.**

Results: **A total of 869 patient-days of accelerometer data were available. Mean total number of steps per day was greater for people with higher walking capacity (6MWT distance, ≥600 m). However, this group spent a small proportion of time walking at higher cadence bands. Compared with people with 6MWT distance of at least 600 m, people walking less than 500 m had approximately half the rate of walking bouts of 5 minutes or longer. Positive mood and fewer exercise barriers predicted more walking bouts of at least 5 minutes.**

Conclusions: **Study participants with MS spent a small proportion of time walking at a health-promoting intensity.** ***Int J MS Care.*** **2020;22:143-150.**

The extent to which a test conducted under controlled clinical or experimental conditions relates to results obtained in the real world is termed *ecological validity*.[1,2] For many health conditions, clinical assessments of physical performance are conducted to ascertain health status, to evaluate effectiveness of interventions, and/or to determine readiness for certain types of interventions, such as surgery.[3] How a person functions when tested clinically and when they are in their natural environment can be quite different. This difference can affect how the result of a functional test is interpreted, which is important not only for clinical care but also in research when functional outcomes provide evidentiary support for new interventions.[4] Because interventions are not targeted to improve a test but to improve the person in their environment, the degree to which the test results are reproduced in a natural environment is an important psychometric property. Ecological validity is rarely assessed primarily because it is very difficult to obtain accurate information about the person's function in their everyday environment. New technology, such as triaxial accelerometers, makes the assessment of real-world function easier, particularly for mobility constructs.[5-7] Clinical tests that sample only a few seconds or minutes out of an infinite time span can introduce misclassification. Some low-functioning people may perform higher from time to time in their real environment, indicating a degree of reserve,[8] which may be an important health indicator. Others may make their best effort clinically and be unable to reproduce this effort outside of the clinic. It may be that, over time, the test result improved but the person did not. In other words, the change in a test result does not necessarily translate to a change in the person's real-life activities.

Capacity is what the person can do, and *performance* is what the person does do. Performance implies a sustained activity, for example, to meet the Canadian Physical Activity Guidelines, which recommend 150 minutes per week of moderate-to-vigorous intensity aerobic physical activity in bouts of 10 minutes.[9]

The difference between "can do" and "does do" can be influenced by mood, motivation, fatigue, and the environment.[10-12] The assumption that clinical capacity is sufficient to indicate walking performance may not hold. Knowing the difference between capacity and performance and what might explain the difference can also indicate targets for therapy, particularly rehabilitation therapies.

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Several studies have related walking tests to habitual everyday walking with the aim of identifying whether these performance outcomes could be used to identify individuals likely to be physically active. Stellmann et al[13] probed whether the results of the 2- and 6-Minute Walk Tests (2MWT and 6MWT, respectively) conducted clinically were reproduced by 2 or 6 minutes of uninterrupted walking during 7 days of monitoring with an accelerometer. In 30 people with MS and an Expanded Disability Status Scale (EDSS) score less than 7, an average of 2.61 bouts of 2 minutes and 0.35 bouts of 6 minutes per day were observed per person during 210 person-days of monitoring.[13] The results indicate some degree of ecological validity for walking bouts of the 2MWT but not of the 6MWT. However, more information on who is able to reproduce 6MWT clinical results in the community is required to develop targeted intervention strategies.

Gijbels et al[14] (n = 50) estimated the extent to which leg muscle strength, walking balance, EDSS score, and self-report physical function were able to predict habitual walking performance recorded using an activity monitor for 7 consecutive days. Walking capacity was measured using the Timed Up and Go test, the Timed 25-Foot Walk test (T25FW), the 2MWT, and the 6MWT. People with MS were grouped as having mild MS (EDSS score, 1.5-4.0) and moderate MS (EDSS score, 4.5-6.5). Habitual walking performance was indicated by stride count. The correlations of the 2MWT and the 6MWT with habitual walking performance were low (0.35 and 0.43, respectively) for people with mild MS and moderate (0.73 and 0.73, respectively) for people with moderate MS. Univariate regression analysis showed that only the 6MWT predicted habitual walking performance (R^2 = 0.187) in people with mild MS, whereas the 2MWT, 6MWT, and T25FW predicted habitual walking performance in those with moderate MS (R^2 = 0.532, 0.527, and 0.387, respectively).The ecological validity of these performance walking tests for step count is much stronger for people with greater MS disability than for people with less disability.

In a sample of 256 ambulatory people with MS, Motl and colleagues[15] correlated EDSS score, Patient-Determined Disease Steps (PDDS) scale score, 12-item Multiple Sclerosis Walking Scale score, T25FW result, and oxygen consumption on the 6MWT with step counts measured using 7 days of accelerometer data. Moderately strong correlations were observed between these clinical outcomes and the accelerometer data: EDSS (–0.52), PDDS scale (–0.55), and 12-item Multiple Sclerosis Walking Scale (–0.62) scores; T25FW result (0.59); and oxygen consumption (0.63). These results suggest good ecological validity when step count is the outcome.

Several other studies associated self-report and performance tests with accelerometer data among people with MS.[13,15-17] In these studies, it is common to report the various parameters from the accelerometer output as mean values, a metric that does not adequately represent walking performance during the day. In a typical day, people may engage in low-intensity walking behavior for activities of daily living as well as some higher-intensity walking for exercise, continuously or interspaced with rest periods. Walking intensity is typically reported as cadence (steps per unit of time). The relationship between cadence and effort is expressed as metabolic equivalents. For example, cadence of 100 steps per minute is equivalent to 3 metabolic equivalents, which is classified as moderate-intensity effort and is the pace recommended to meet Canadian Physical Activity Guidelines.[9] In addition, there are other factors that act as barriers or facilitators to translating walking capacity to walking performance, such as mood, motivation, fatigue, and the environment.[10-12] The present study was designed to investigate some of the gaps in the literature about how clinical tests translate into walking performance in the community, considering different metrics for performance and characteristics of the individuals where there is a greater or lesser degree of match.

Knowing the difference between capacity and performance can indicate targets for therapy, particularly rehabilitation therapies. The assumption that clinical capacity is sufficient to indicate walking performance may not hold, indicating that clinically assessed walking capacity may lack ecological validity. The global aim of the study was to illustrate methods for validating clinical tests of walking capacity against real-world performance in people with MS. Mobility in MS is of particular interest as results of walking tests are used to rate severity and evaluate treatment outcome.[4] Compared with stroke, Parkinson disease, or arthritis, MS is a condition of younger people, and, hence, assessing physical function is not confounded by physiological effects of aging that will affect both capacity and performance.[18] Specifically, the objective of this study was to estimate for people with MS the extent to which walking capacity tested in the laboratory using the 6MWT is reproduced

during 7 days of free-living step monitoring using an accelerometer and how this relationship is affected by age, sex, motivation, exercise enjoyment, and barriers to participation.

Methods

Study Design

The data for this study came from the first assessment of people with MS recruited for a trial on the role of exercise in modifying outcomes for people with MS.[19] After assessment on the 6MWT, participants were fitted with an accelerometer on the right thigh to be worn for 7 consecutive days. Ethical approval was obtained from the ethics review board of the Montreal Neurological Institute at McGill University Health Centre–Research Institute (Montreal, QC, Canada).

Study Population

Trial participants were recruited from two university-based MS clinics. People who were diagnosed as having MS after 1995, were aged 19 to 65 years, and were independent in ambulation without use of a walking aid (PDDS scale stage: early cane) were eligible. Only people diagnosed after 1995 were included so as to have a more homogeneous group of participants with respect to diagnostic criteria and access to disease-modifying therapies.[5,20,21]

Measures

The full measurement strategy is given in the published protocol.[19] Walking capacity was measured using the MS-specific version of the 6MWT.[22] The individual walks back and forth on a marked course of 20 m with standardized instructions to walk as fast as possible without jogging or running; rest periods were allowed. The data obtained are distance covered in 6 minutes and the ratio of the distance in the first minute to the distance in the last minute, used as an indicator of fatigability.

Walking performance in everyday life was measured using accelerometers (activPAL3; PAL Technologies Ltd, Glasgow, Scotland). Accelerometer output, recorded every 1/20 second, included time spent standing, time spent doing any stepping, and time spent in different cadence bands (0-10, 10-20, 20-30 ... 90-100, etc). Accelerometers have excellent psychometric properties in people with MS and are considered a feasible and acceptable tool to measure physical activity.[5,6,23]

Also measured were factors affecting walking performance. Physical function, mood, and motivation were assessed using subscales of the RAND 36-Item Health Survey 1.0 (RAND-36).[24] Motivation was assessed using the Vitality subscale of the RAND-36[24] because no specific motivation measure was available and having energy for the desired activity is a component of motivation,[7] exercise barriers and benefits,[25] self-efficacy,[26] and exercise enjoyment. Age, sex, and disability status were also recorded.

Data Analysis

Cadence values from the accelerometer were grouped into bands based on meaningful categories from the literature.[27,28] To relate the distance covered during the clinical 6MWT (measured in meters) to community-based walking performance (expressed in steps per minute or cadence), five distance categories were used (<300, 300 to <400, 400 to <500, 500 to <600, ≥600 m) to match cadence bands.

Mean number of steps (per person per day), mean number of these steps at a brisk cadence or faster (≥100 steps per minute), and cumulative time per week spent walking at a brisk cadence or faster were regressed on categories of 6MWT using quantile (median) regression. Contiguous steps were grouped into bouts of less than 5 minutes and bouts of 5 minutes or longer, and number of bouts 5 minutes or longer was regressed on categories of 6MWT using a zero-inflated Poisson (ZIP) model. All the models were tested univariately (only categories of 6MWT) and then were adjusted for age, sex, vitality, mental health, exercise barriers, self-efficacy, and exercise enjoyment. To be compatible with guidelines from the American Statistical Association, this article avoids presenting *P* values or referring to findings as statistically significant.[29]

Results

Table 1 shows that the sample had a mean ± SD age of 45.4 ± 10.0 years, was predominantly women (78%), and had a diagnosis of the relapsing-remitting type of MS (67%). Also shown are values on the RAND-36 subscales, including normative values from the Canadian population.[30]

Table S1, which is published in the online version of this article at ijmsc.org, presents the distribution of daily steps, cadence, and proportion of time spent walking at different intensities according to categories of 6MWT. A total of 869 patient-days of accelerometer recording were available (mean, 7 patient-days) for 12 hours per day. The 6MWT distance was converted to cadence

Table 1. **Demographic characteristics of study population (N = 125)**

Variable	Value
Age, y	45.4 ± 10.0
Sex, women/men	98/27 (78/22)
Time since diagnosis, y	6.1 ± 3.4
Type of multiple sclerosis	
Relapsing-remitting	84 (67.0)
Secondary progressive	3 (0.2)
Primary progressive	3 (0.2)
Primary relapsing	3 (0.2)
RAND-36 subscales (0-100) [normative values]	
Physical Function Index [88]	72.5 ± 23.3
Mental Health Index [77]	67.5 ± 16.5
Vitality [66]	48.9 ± 20.9
Exercise barrier (0-4)	2.2 ± 1.1
Self-efficacy (20-70)	51.6 ± 10.5
Exercise enjoyment (0-10)	6.6 ± 2.5

Note: Data are given as mean ± SD or number (percentage).

to be comparable with accelerometer data. People with the shortest 6MWT distance (<300 m) walked a mean ± SD of 4130 ± 906 steps per day. Approximately 10% of steps were classified as incidental (<39 steps per minute), 18% of steps as purposeful (40-59 steps per minute), 30% as slow walking (60-79 steps per minute) and medium walking (80-99 steps per minute), and only 11% as brisk walking and faster (≥100 steps per minute). In the community, 30% of the steps were at the same cadence band (shaded box) as the 6MWT value (concordant cadence band), and 42% of the steps were at a higher cadence. For the people in the other 6MWT groups, as cadence increased, the proportion of steps at or exceeding this band decreased. For people in 6MWT categories of 300 to <400 m, 400 to <500 m, 500 to <600 m, and ≥600 m, the percentages of steps at the concordant band were 32.8%, 29.3%, 12.2%, and 20.5%, respectively. The proportions of steps greater than clinically measured cadence were 42.6%, 27.4%, 7.9%, 0%, and 0%, respectively.

Also shown in Table S1 is that the distribution of the duration of walking bouts did not differ by walking capacity. Although the total number of steps taken per day was greater, on average, for people with higher walking capacity, they did not allocate these steps toward walking for longer durations. To illustrate, people who walked less than 300 m spent an average of 50.7% of their daily upright time (standing and stepping) walking in short bouts of 1 minute. The average duration of vertical time (standing and stepping time) per day increased across the group of patients who walked less than 300 m to the group who walked 600 m or more; there was no difference in the proportion of time allocated to longer bouts of walking. Figure 1 displays the data in Table S1 as a stacked bar graph showing the proportion of steps at different cadence bands contributing toward the recommended total of 10,000 steps for healthy people.

Table S2 shows the results of quantile and ZIP regression analysis, both unadjusted and adjusted models, comparing walking outcomes across the five categories of walking cadence, derived from the 6MWT. The distribution of daily step counts was not normally distributed consistently across categories of 6MWT cadence values, necessitating a quantile regression model. The median was chosen, and the regression parameters are interpreted as the estimated difference from the median of the highest group. The adjusted quantile model was different for all three categories of walking capacity (<300, 300 to <400, 400 to <500 m). For the outcome of cumulated time at a brisk cadence or faster, the median values ranged from 17.4 to 27.6 minutes. The unadjusted quantile regression model showed differences for any categories of 6MWT.

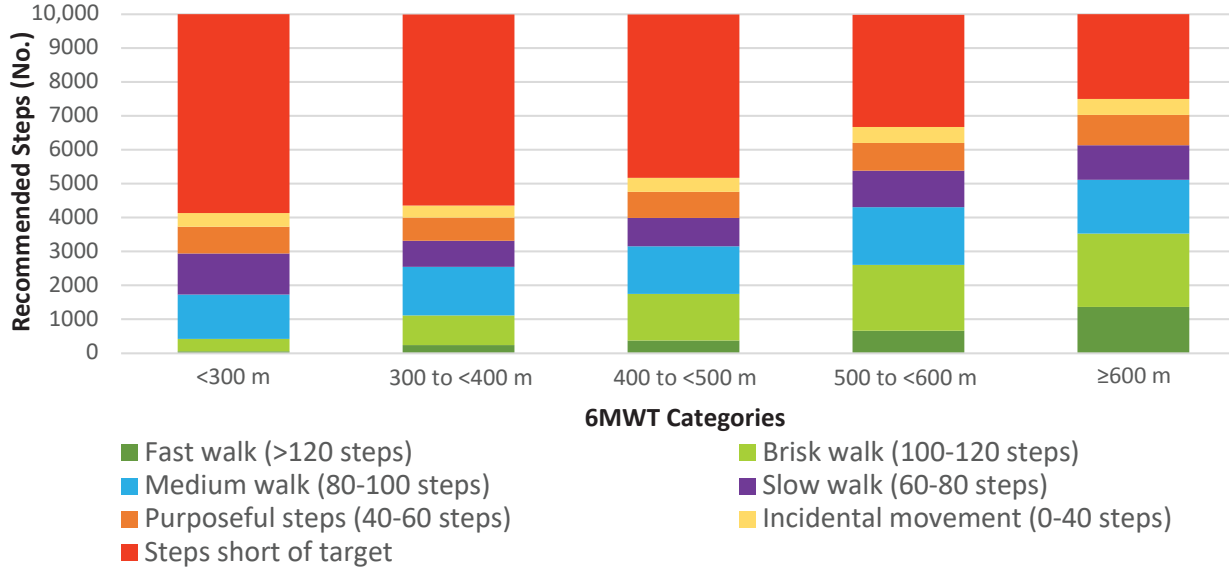

Figure 1. **Proportion of steps at different cadence bands contributing to recommended target steps (10,000 per day)**

6MWT, 6-Minute Walk Test.

The total number of bouts lasting at least 5 minutes over 7 days ranged from 209 for all the persons in the lowest 6MWT category to 1030 for all those in the highest category. Per person, the median values across the 6MWT categories were 36, 41, 48, 66, and 71, respectively; the overall mean (median) per person was 57 (56.5). The rates per 1000 waking hours were 10.36 for the lowest 6MWT category and 11.44 for the highest. The unadjusted and adjusted relative risks for the lowest three categories were similar to each other and statistically lower than those of the highest category. There was no trend for increasing rates of walking bouts of at least 5 minutes across categories of 6MWT (P = .2). For the lowest category, the relative risk is interpreted as reducing the expected number of bouts by 0.59, where the expected number is the overall mean. The ZIP model showed statistical significance on two categories of 6MWT (300 to <400 m and 400 to <500 m). There were no differences in number of walking bouts between the groups with the highest walking capacity (500 to <600 m and ≥600 m). However, people walking less than 500 m accumulated approximately half of the walking bouts of those walking 600 m or more. Table S3 shows the estimates for quantile and ZIP regression analysis (adjusted and unadjusted) values for all variables under study. More positive mood and fewer exercise barriers (odds ratio presented for more exercise barriers) were associated with more walking bouts of at least 5 minutes.

Discussion

The results of this study showed that people with MS spent only a portion (12.2%-72.5%) of their usual day walking at a pace equivalent to or greater than the pace assessed clinically using a walking performance test. Not surprisingly, people with more severe walking disability (6MWT <300 m) showed more consistency between free-living walking and that assessed clinically (72.5% of steps greater than or equal to clinically measured 6MWT) because they have limited capacity to increase their walking pace. Bohannon[31] reported normative values for fast and comfortable gait speed by age and sex using older age as a proxy for greater walking limitations. The ratio between the fast and comfortable was 1.67 for younger people and 1.56 for people older than 70 years, and people with lower walking capacity also had a limited capacity to walk at a faster pace.[31]

However, people with MS with greater walking capacity (≥500 m on the 6MWT) walked less frequently at the measured pace outside of the clinic (12.2%-20.5%). The clinically assessed walking test used herein was the 6MWT, and Table S1 also shows that this duration of walking was rare in the community and, when performed, the cadence was much lower than that assessed clinically. Although the total number of steps taken per day was greater, on average, for people with higher walking capacity, they did not distribute these steps toward walking for longer durations. To illustrate, people who walked less than 300 m spent an average of 50.7% of their daily upright time (standing and stepping) walking in short bouts of 1 minute, similar to those with higher capacity.

For the most part, people with different categories of 6MWT distance differed on their median values for all walking outcomes except bouts, where there was no trend across higher categories of the 6MWT. This finding is important and points out that despite the greater number of steps and brisk steps across the categories of the 6MWT, people of different capacities did not walk longer. The ecological validity of the clinically assessed 6MWT translates more to number of steps, number of steps at a brisk pace or faster, and cumulated time per week at a brisk pace or faster but does not translate to greater engagement in health-promoting walking, as shown by the effects on 5-minute walk bouts. Two variables were associated with walking bouts: better mood and fewer exercise barriers. This suggests that translation of walking capacity to performance is perhaps more complex and could be mediated by other variables. Thielman et al[32] analyzed data from the Canadian Health Measures Surveys on neighborhood walkability and accelerometer-measured physical activity in 7180 respondents. The study found that people with access to walkable neighborhoods were able to accumulate approximately half to two-thirds of the amount recommended in Canadian Physical Activity Guidelines compared with people with access to the least walkable areas.[32]

In a report summarizing data from 786 people with MS accumulated across several studies by Motl et al,[16] accelerometer data were used to link steps per day to disability level. There was an incremental decline in the average number of steps taken per day, with increasing disability measured using the PDDS scale. People without activity-limiting MS-related disability (PDDS scale score = 0) walked on average 7500 steps per day; people with some activity limitation from MS but no walking

disability (PDDS scale score = 1 or 2), 6600 steps per day; people with walking disability, 5200 steps per day; people needing a unilateral walking aid, 3500 steps per day; and people needing bilateral support, 2000 steps per day. These data support that approximately 1000 steps per day could be considered a clinically important difference.[33] In the present study, steps per day ranged from 4000 for people walking less than 300 m in 6 minutes (equivalent to some walking disability; 41.7% of predicted) to 7500 for people walking 600 m or more (97.5% of predicted) in 6 minutes and are concordant with those from Motl et al.[16] Thus, the results of laboratory tests of walking capacity for people with MS are not an accurate reflection of walking performance needed to go beyond activities of daily living and to achieve the health benefits of walking.

The ultimate goal of therapeutic intervention in MS is to reduce lesion burden and preserve function in everyday life. An important goal of rehabilitation for people with MS is to improve capacity for function as a way of combating progressive decline and to promote physical activity to improve overall health. The health benefits of physical activity[34] in terms of physical, cardiovascular, and mental health are well-known and apply to people even with disabilities.

There is great interest in measuring and promoting physical activity among all people, regardless of capacity (inclusive society).[35] Use of technology, such as wearable sensors, has increased opportunities for promoting physical activity in vulnerable populations. From the point of view of innovation, this project will form the basis for further developing wearable sensors to provide real-time feedback on cadence bands during walking performance. The use of cadence as a target measure of walking performance is understandable by most people. Walking at a cadence band is a realistic goal for people with MS to practice in the community with the target goal to walk one level greater than the cadence band–tailored walking target. Walking could be an effort for people with a disability because self-initiated walking at a health-promoting intensity requires capacity, opportunity (time and safe space to practice), and motivation.[36] We showed herein that capacity is more related to step counts than duration of walking and that mood and barriers affect duration rather than step counts. Measurement beyond daily steps is recommended when using physical activity monitors because cadence and duration of walking bouts provide actionable features of physical activity.

Thus, the results of clinical tests of walking capacity for people with chronic health conditions may not be an accurate reflection of walking performance needed to achieve the health benefits of walking. This study indicates that the ecological validity of clinically assessed walking tests does not hold for people with MS with higher capacity.

This study has several limitations. Similar to other studies that have looked into measuring walking in people with MS, this study was a planned analysis of people recruited into an exercise trial. This limits the generalizability of this study's findings because people may have been more motivated to exercise and have fewer exercise barriers than the general MS population. This may explain why some variables were associated with walking outcomes except duration. In addition, not all variables affecting real-life performance were available, notably neighborhood walkability.

In conclusion, what people with MS "can do" and what they "do do" are not the same. People with MS in this sample had a very small proportion of walking bouts of 5 minutes or longer irrespective of the intensity. Closing the gap between tested walking capacity and community walking performance could be an achievable physical activity goal for people with chronic health conditions. □

PRACTICE POINTS

- People with MS with greater walking capacity (≥500 m on the 6-Minute Walk Test) rarely walked at the measured pace outside of the clinic, and neither did they use these steps toward walking for longer durations.
- Having better mood and fewer exercise barriers did not affect the mean number of steps per minute but did affect the number of walking bouts of at least 5 minutes, indicating that mood and exercise barriers should be optimized before making exercise recommendations.
- Measurement beyond daily steps is recommended when using physical activity monitors because cadence and duration of walking bouts provide actionable features of physical activity.

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