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分担研究報告書

エビデンスに基づいたロコモティブシンドロームの対策における簡便な確認・介入方法の確立と普及啓発体制の構築に資する研究（19FA1017）

【疫学研究】Simple Mobility Tests Predict Use of Assistive Device in Older Adults

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Abstract

Background: Assistive devices for ambulation (ADA) are commonly provided to improve safety and independence in older adults. Despite the common use of these devices, there is no standard prescribing guidelines and non-healthcare providers, including caregivers and family members, make decisions about the need for ADAs. Identifying factors or a single screening test associated with ADA use would benefit clinicians and non-healthcare caregivers in making decisions to adopt ADAs for patients, clients, and family members. **Purpose/Objectives**: The purpose of this cross-sectional study was to identify the test that best predicts ADA and non-ADA use among community-dwelling individuals and assistive-care beneficiaries. **Methods**: A total of 85 older adults (81.6±8.2 years old) who underwent outpatient physical therapy participated in this study. They participated in a series of tests, including the Timed and Up and Go, handgrip and quadriceps strength, the 30-second Chair Rise Test, 5-meter fast gait speed, the functional independence measure, the Locomotive Syndrome Tests (Stand up test, 2-step test (2ST), and the Locomo-5 questionnaire), and numeric pain scales. Mann-Whitney U tests were used to differentiate between ADA users and non-users. A logistic regression analysis was applied to examine which test best predicted ADA use for each clinical assessment.

Results: 80% of participants (n=68) used an ADA. There were significant differences in all test variables between users and non-users (P = 0.033-P < 0.001), except for quadriceps strength, age, and pain (all P > 0.05). A logistic regression analysis identified only the 2ST was associated with the prediction equation (P = 0.048), with a cut-off value of 93% of body height (Sensitivity: 72%, Specificity: 82%). **Discussion**: Simple functional measures differentiated between physical function, balance, and ADL independence between those who did and did not use ADAs. However, of these tests, only the 2ST predicted ADA status. This is a simple clinical test that evaluated the length a patient can step without losing his or her balance. Individuals who are unable to step 93% of their body height may benefit from an assistive device. **Conclusions**: If comprehensive clinical evaluations are not available to make decisions about ADA use, the 2ST can be used to make clinical recommendations for ADA.

A．Purpose/Hypothesis

Physical disability is a global issue, affecting approximately 15% of the world's population.[1] People with physical disabilities commonly use assistive devices for ambulation (ADA), which can improve basic mobility and improve quality of life.[2-7] Canada reported that nearly 80% of people with disabilities use ADA, which has doubled in the last decade.[8] Although the need for medical devices is increasing, non-healthcare, such as caregivers or family members, often make decisions about ADA use based on patient preference and socioeconomic factors.[3] This can have negative consequence; those who use a device when it is not necessary may impede other motor tasks, and those who do not use one may be at a greater risk of falling or functional impairments. [2, 9]

Physical therapists (PTs) often prescribe ADAs for elderly patients as part of a plan of care. The decision to use an ADA is made after a comprehensive evaluation that often includes an assessment of intrinsic factors (muscle strength, balance ability, and cognitive levels), extrinsic factors (home and community environment) and psychological factors (resistance to ADA usage). This evaluation requires clinical experience, training, and the space and resources of a typical clinic environments.[6] A simple test to determine who would benefit from ADA would increase appropriate ADA prescription and among non-healthcare providers and potentially lead to better outcomes.

These tests have been designed to be performed by healthcare professionals as well as those without significant medical training. While there are many tests that can be used to screen patient function and abilities, the Locomotive Syndrome (LS) Tests have been recently developed to detect subtle age-related mobility decline in older patients. The LS tests include two performance-outcome measures and one self-report questionnaire to assess physical function. Studies have shown that results from the LS tests are significantly associated with mobility decline, poor balance, muscle weakness, and perceived physical functional limitations, while also differentiating between independent community-dwellers and assistant-care beneficiaries. Therefore, it is possible that the LS tests can also be used to screen patients for the need for ADA.

The objective of this study was to determine if physical examination tests can differentiate and predict those who do and do not use an ADA in elderly community-dwelling adults. We hypothesized that performance-based LS tests will be able to predict ADA use.[3]

B．METHODS

This cross-sectional study was conducted among independent community dwellers who participated in a structured rehabilitation program at Kameda-Medical Center in Chiba Prefecture, Japan. A total of 85 elderly patients participated in this study (women: n=54, age: 81.6±8.2 years old). Inclusion criteria included independent community dwellers 65-years-old or older currently undergoing outpatient geriatric-rehabilitation sessions supported by governmental community-care benefits in Japan. Exclusion criteria included people unable to ambulate independently at home or those with cognitive impairments defined as a Mini-Mental State Examination Score (MMSE) below 21.

After confirming understanding of the study's purpose and testing procedures, all participants provided written informed consent approved by the Institutional Review Board at Kameda-Medical Center (#17-037-171129). Research PTs collected data during the tri-monthly physical therapy evaluations from November 2017 to February 2018. Research PTs performed chart reviews to examine whether participants used any ADA and blindly classified participants into two groups (ie, non-ADA and ADA). They gathered participant information, including age, sex, anthropometric data (ie, body height and weight), and beneficiary class. In addition to the LS tests, we selected four primary determinants for clinical decisions for ADA usage, including pain, balance, muscle strength, and physical function.

They participated in a series of tasks to assess numeric pain scales, including Timed and Up and Go, handgrip, quadriceps strength, the 30-second Chair Rise Test, 5-meter fast gait speed, functional independence measure, and the Locomotive Syndrome Tests (Stand up test, 2-step test (2ST), and the Locomo-5 questionnaire).

Due to heterogeneous data distribution, Mann-Whitney U tests and Chi-square tests for independence were used to describe clinical differences between groups (those who do and do not use ADA). A logistic regression analysis with forced entry was applied to examine the best prediction of ADA usage for each clinical assessment. The significant predicting tests then independently created the Receiver Operating Characteristic Curve to examine clinical validity, including clinical threshold, sensitivity, and specificity. The alpha levels were set as 0.05. All data analyses were processed using SPSS statistical software (SPSS version 24, IBM. Inc.).

C. Results

Sixty-eight participants (80%) used an ADA . Women were more likely than men to use ADA (70.6%, P = 0.007). There was no significant difference between non-ADA and ADA groups in the frequency of disability levels, those receiving governmental support care, or other demographic characteristics, such as age and anthropometry (P > 0.050; **Table 1**).

Table 2 indicates the clinical characteristics of ADA users and non-ADA users. ADA users demonstrated significantly slower TUG than non-ADA users (⊿: 4.0sec, P < 0.001). ADA users showed significant muscle weakness in handgrip (⊿: 23%, P = 0.030) but not in quadriceps (⊿: 5%, P > 0.050). Both GS and FIM were significantly different between groups as ADA users showed slower gait (⊿: 0.39m/s, P < 0.001) and severe disability in physical function (⊿: 3, P = 0.033). All LS tests showed significant differences between ADA and non-ADA users. The numeric score for the SUT was significantly lower in ADA users (⊿: 1, P < 0.001). The 2ST had a lower score in ADA users (⊿: 0.37, P < 0.001). The Loco-5 had a significantly higher ADA user score (⊿: 5.0, P < 0.001).

As a result of the logistic regression analysis, only 2ST was significant (OR: 0.004 [95%CI:

0.00-0.96], P = 0.048). Since change in one unit of body height is not physiologically likely for this test, we also calculated the odds ratio based on a change of one standard deviation (2.8% of body height). For an increase in one standard deviation there was a 14% reduction in risk [OR: 0.86 (95%CI: 0.73-0.99)] (**Table 3**). According to predicted ADA use, when the ROC curve was created for 2ST, the AUC was 0.86 (95%CI: 0.76-0.95) with a cut-off value of 0.93 (Sensitivity: 72%, Specificity: 82%, **Figure 1**).

Table 1 Comparison Between Two Groups of the Basic Attribute

Sociodemographic Data	All Participants (n = 85)	No Assistive Aid (n = 17)	Assistive Aid (n = 68)	*P* values
Men, n (%)	31 (36.5)	11 (64.7)	20 (29.4)	.007[a]
Women, n (%)	54 (63.5)	6 (35.3)	48 (70.6)	
Age, median [interquartile range], y	84.0 [75.5-87.0]	78.0 [74.5-85.5]	84.0 [77.0-87.0]	.478[b]
Height, median [interquartile range], cm	153.0 [146.0-161.5]	157.0 [150.0-167.8]	152.0 [146.0-160.0]	.090[b]
Weight, median [interquartile range], kg	52.8 [44.6-61.3]	58.1 [44.5-65.4]	51.4 [44.7-60.5]	.325[b]
Disability level Support Level, n (%)	28 (32.9)	7 (41.2)	21 (30.9)	.419[a]
Disability level Care Level, n (%)	57 (67.1)	10 (58.8)	47 (69.1)	

[a] X^2 test

[b] Mann-Whitney U Test

Table 2 Comparison between two groups of the physical functions

physical functions	All Participants (n = 85)	No Assistive Aid (n = 17)	Assistive Aid (n = 68)	*P* values
Pain during movement [a]	2 [0-4]	0 [0-5]	2 [0-4]	.458
TUG, s	12.8 [10.1-16.7]	9.5 [8.2-10.6]	13.5 [11.2-18.9]	< .001
HGS, kg	17.5 [14.3-22.1]	21.0 [18.6-26.2]	16.3 [13.6-21.9]	.030
WBI, kg/kg	0.37 [0.27-0.43]	0.42 [0.31-0.50]	0.37 [0.25-0.43]	.083
30sCRT, times	10.0 [8.5-12.0]	12.0 [9.5-13.0]	10.0 [8.0-12.0]	.046
Gait speed, m/s	0.96 [0.80-1.25]	1.26 [1.07-1.66]	0.87 [0.77-1.14]	< .001
FIM total score	118 [112-122]	119 [117-123]	116 [110.0-121]	.033
SUT	2 [1-3]	3 [3-4]	2 [1-2]	< .001
2ST	0.85 [0.60-1.02]	1.16 [0.94-1.24]	0.79 [0.51-0.96]	< .001
Loco-5	9 [6-12.5]	6 [2-8]	11 [7-13]	< .001

All results are presented as median [interquartile range]

a Self-reported pain in the lower extremities during movement anchored with 0 (no pain at all) and 10 (unbearable pain)

Abbreviations: TUG, Timed Up &Go; HGS, Handgrip strength; WBI, Quadriceps Femoris (nomalized by body weight); 30sCRT, 30s Chair Rise Test; FIM, Functional Independence Measure; SUT, Stand up Test; 2ST, Two-step Test; Loco-5, Locomo-5 checklist.

Table 3. As a result of logistic-regression analysis that assumed walk aid use or nonuse a dependent variable

Factor	Odds ratio	95%CI	*P* values
Sex	4.88	0.46-51.76	.189
TUG	1.16	0.74-1.80	.521
HGS	0.99	0.85-1.16	.888
30sCRT	1.47	0.85-2.55	.173
Gait speed	0.41	0.02-9.42	.408
FIM	0.97	0.84-1.13	.734
SUT	0.40	0.15-1.09	.072
2ST	0.86	0.73-0.99	.048
Loko-5	1.18	0.95-1.47	.128

Abbreviations: CI, Confidence interval; TUG, Timed Up & Go; HGS, Handgrip strength; 30sCRT, 30s Chair Rise Test; FIM, Functional Independence Measure; SUT, Stand up Test; 2ST, Two-step Test; Loco-5, Locomo-5 checklist.

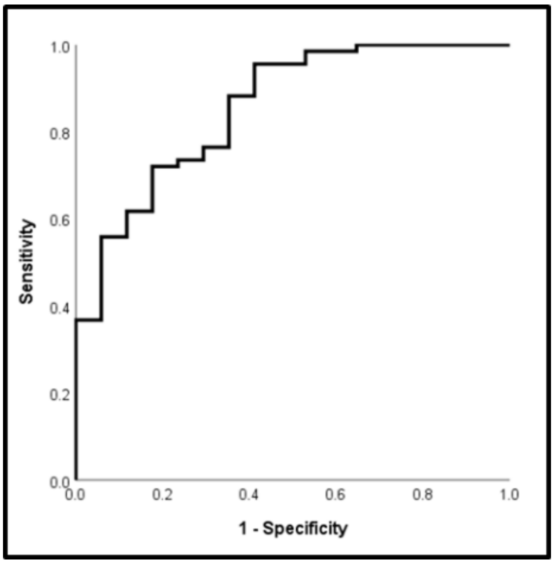

Figure 1 ROC curve of the 2ST about the use presence or absence of ADA.

D. Discussion

Most all of the measures in this study were different between those who do and do not use an ADA. Interestingly, age and pain levels were not found to be different among ADA and non-ADA users, although these factors are commonly considered determining factors in prescribing ADA for older adults. Among the tests evaluated in this study, only the 2ST predicted ADA status. Using the ROC analysis, a score of 0.93 (equal to 93% of the subject's body height) was found to be the best predictor of ADA use. (72% of sensitivity and 82% specificity). This value is clinically meaningful and is similar to other cut-off values for the 2ST. For example, 96% of body height in 2ST was predictive of individuals who met the Japanese definition of frailty (ambulation less than 1.0m/s). A 2ST score below 100% of body height was also associated with falling and falling anxiety, which may also support why the 2ST was predictive of ADA use. Furthermore, the mean value of 2ST for the participants was 0.81±0.28 and the OR of 2ST predicting the use of ADA was 0.86, when based on change in one standard deviation of 2.8% of body height. Therefore, if we assume the average height in an elderly population is 170 cm, one standard deviation in the 2ST equates to 4.76 cm. For every 4.76 increase in 2ST distance, there is a 14% reduction in the need for an assistive device for this population.

The 2ST is often used to assess overall ambulatory ability, as it is significantly correlated with self-selected and maximal walking speed, as well as six-minute walking distance. However, walking speed and the Six-Minute Walk test require substantial space to perform. The 2ST can be performed in a small space, such as a clinical examination room, which may favor the feasibility of this test in ADA screening and prescription. The 2ST can also be normalized by body height, which reduces the ceiling and floor effects of this test and may account for biological differences in sex and age.[11]

There are a few limitations in this study. First, the regional sampling might limit generalization to other locations and countries because of different care systems for assistive beneficiaries. Secondly, our patients were independent community dwellers, but were currently participating in physical therapy for various pathologies. This may have provided a sample with lower physical function than independent community dwellers in general. However, the functional disabilities in this group were mild to moderate among the general age group as individuals in assistant living facilities or those who required assistive-care were excluded from the study. A study with a larger sample to examine deterioration of physical function and ADA use in an age-stratified sample is needed. Finally, there is a slight limitation for the generalization of our results into US practice. Due to the Japanese comprehensive community rehabilitation care systems, older people are more likely to obtain ADA through non-healthcare individuals. However, administration of ADAs should be a significant concern for family-caregivers for older adults in the global population.

Despite the limitations, the outcomes of this study are clinically important. The 2ST is a simple and easy screening that can be performed by non-clinician caregivers and clinicians working in a limited space. The clinical thresholds, below 93% of the body height, can guide these testers to consider or refer to PTs for further comprehensive assessments for proper ADA prescription. PTs can also use the results of the 2ST as part of their clinical decision making for determining ADA needs and reducing fall-risk among community-dwellers. Validating the clinical implementation of this 2ST threshold (93%BH) is needed in future studies. Future work should examine the clinical effectiveness of using this threshold for providing ADA in terms of reducing risk of fall or improving physical function.

Ｅ．**Conclusions:**

ADAs are commonly administrated medical devices that improve balance and ability and reduce pain during physical performance. This study examines whether functional tests can differentiate ADA users' and ADA non-users' status to identify the most predictable screening test. Only 2ST could significantly predict the ADA status, with the clinical cut-off as 93% of the body height. This simple screening should be implemented in community and wellness programs to guide physical therapists' comprehensive evaluations.

Ｆ．研究発表

1. 論文発表

投稿中

（Journal of Geriatric Physical Therapy）

2. 学会発表

準備中

G．知的財産権の出願・登録状況

1. 特許取得

該当なし

2. 実用新案登録

該当なし

3.その他

該当なし

H. 引用文献

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