INTRODUCTION

Previous studies have found that outcome measures such as lower-limb muscular strength,1-3 balance,4-8 walking speed,9-14) and cognitive function15,16) are related to walking independence in elderly persons and in patients with stroke disease. However, outcome measures related to walking independence in patients with medical diseases have not been reported. Consequently, we cannot estimate the likely walking independence for patients with medical diseases. As a result, mobilization is often delayed in the acute phase, and this can lead to disuse syndrome and increase the care burden.

To investigate walking independence, previous studies have evaluated lower limb muscular strength, balance, walking speed, and cognitive function. Lower limb muscular strength can be tested using devices such as a handheld dynamometer17) or isokinetic dynamometers18); balance can be evaluated using the functional reach test,19) the Berg balance scale,20) or the timed up-and-go test21); walking speed can be evaluated using the 10-meter walking test, among others12); and cognitive function can be evaluated using tests such as the mini-mental state examination (MMSE).22) These globally used tests are valid and reliable. However, they require a measuring instrument, a suitable place to carry out the measurement, and can be time-consuming. Therefore, practically speaking, these tests are not suitable for use in inpatients in the acute phase of a disease, when, for example,
patients are receiving treatment via an intravenous bedside drip. Quick and simple tests that can be used in inpatients in the acute phase of a disease are desirable. Moreover, tests that can be used with a wide range of diseases would be advantageous because the medical diseases observed in the physical therapy field are diverse. In the current study, we investigated outcome measures and established cut-off values that can quickly and simply test the walking independence of inpatients with a medical disease in acute care hospitals.

**METHODS**

**Study Design**

This cross-sectional study was performed according to the principles of the Declaration of Helsinki. The institutional review board approved the study, and informed consent was obtained from all patients. Data collection was performed from April 2012 to December 2014.

**Subjects**

We included 200 patients aged 20 years or older who had a medical disease and were admitted between April 2012 and December 2014. The inclusion criteria were inpatients with a medical disease who had not undergone orthopedic surgery for conditions such as a transformation or fracture, patients without a central nervous system disease, and patients who could walk. The exclusion criteria were patients with the symptoms of severe paralysis, cerebellar symptoms, severe spinal cord symptoms, recent surgery for an orthopedic disease, a mental disorder, difficulty with understanding instructions, a diagnosis of dementia, and walking limited by a breathing or circulatory system condition. Of the patients whose physicians had requested physical therapy because they judged that rehabilitation was necessary for the improvement of muscular strength or the prevention of walking ability deterioration, and whose rehabilitation physician permitted intervention for rehabilitation, 224 underwent evaluation of their physical function. Of these patients, 24 met the exclusion criteria, so a total of 200 patients were included in the study.

**Measurements**

The following information was collected from patients’ medical records: sex, age, height, body weight, body mass index (BMI), and diagnosis. Measurements were performed for all patients after the introduction of rehabilitative training. In addition, the walking independence of each patient was evaluated, and all the other measurements were done on the same day.

**Walking Independence**

Walking independence was evaluated using the functional independence measure (FIM)\(^{23}\): 6–7 points indicated walking independence, whereas 1–5 points indicated non-independence. The use of a walker was not permitted; however, we permitted the use of aids such as a cane, which are used in everyday life, to eliminate any bias resulting from allowing the use of an assistive device.

**Physical Characteristics**

**Straight Leg Raising Repetition Count**

As an index of lower limb muscular strength, we used the straight leg raising (SLR) test, which is an exercise that physical therapists use frequently in the clinical setting. SLR is an exercise that can be performed on a bed regardless of a patient’s level of movement. SLR requires muscle activity from the hip joint flexor and primarily from the abdominal muscle as well as knee extension.\(^{24,25}\) It is used for muscle strength training of the lower limbs and it serves as an index for muscular strength of the lower limbs and the trunk. Furthermore, SLR has characteristics that are easy to quantify, i.e., the number of SLR repetitions.

The measurement position was with the patient supine with the arms folded over the trunk. Subjects raised their lower limb in a knee extension and ankle dorsiflexion position, and the contralateral lower limb was in an extension position on the bed. We counted the movement once in elevation with a hip joint flexure of 30°. The measurement was performed at a frequency of once per 2 s (raise the leg up for 1 s and place it down for 1 s). The time was measured until subjects were not able to lift their legs anymore, until subjects were not able to reach a hip joint flexure of 30°, or until the knee of the raising leg was obviously bent (the maximum number of repetitions was 30). Measurements were performed for each leg, and the largest value was used as the number of repetitions for each subject.

**One-leg Standing Time**

To measure patients’ balance, we used the one-leg standing time (OLST), which can be performed easily without any equipment.\(^{26}\) To perform the measurement,\(^{27}\) patients were instructed to keep their eyes open while in the one-leg standing position in which one foot was slightly raised from the floor and their upper limbs remained hanging down. The time until the raised leg was set back down on the floor was measured, with a maximum time of 30 s recorded for those
who could stand on one leg for at least that length of time. Measurements were performed three times each for the right and left legs, and the largest value of the three measurements was used as the OLST for each subject.

Cognitive Status
– Mini-Mental State Examination

Cognitive status was measured using the MMSE. This test contains different questions that are grouped in seven categories, each of which is designed to assess specific cognitive functions: orientation to time (5 points), orientation to place (5 points), registration (3 points), attention and calculation (5 points), recall (3 points), language (8 points), and visual constructive capacity (1 point). The MMSE score ranges from a minimum of 0 to a maximum of 30. However, it takes time to carry out the full MMSE.28 Therefore, in this study, orientation, attention and calculation, and repetition, which have the highest correlations with the total score of the full MMSE of the seven categories,29,30 were used to perform the measurement quickly and easily.

Blood Test Data

The following blood test data were obtained from the medical records: total protein (TP) (g/dL), albumin (Alb) (g/dL), red blood cell (RBC) (g/dL), and hemoglobin (Hb) (g/dL) levels.

Statistical Analysis

An unpaired t-test was used to compare the TP and Alb levels between the walking independence group and the non-independence group. The Mann-Whitney U-test was used to compare the age, BMI, SLR repetition count, OLST, MMSE score, and the levels of RBC and Hb between the two groups. The \(\chi^2\) test was used to compare the sex between the two groups. Then, to determine which outcome measures were related to walking independence, logistic regression analysis was performed using variables that were significantly different according to the univariate analysis. We assessed multicollinearity before performing the logistic regression, and variables with a weaker association to the outcome were eliminated from the independent variables. Variables were chosen using stepwise forward regression by a likelihood ratio test. Adjustments for confounding factors were made. In the first model, crude odds ratios (OR) and their 95% confidence intervals (CI) were calculated; in the second model, we adjusted for age, sex, BMI, and diagnosis. Furthermore, receiver operating characteristic (ROC) curve analysis was performed for the items selected according to the multiple logistic regression analysis. The area under the curve (AUC), sensitivity, and specificity were calculated for the cut-off values. Each cut-off value was determined as the point with the minimum distance from the upper left corner of the item's ROC curve. Statistical analyses were performed using SPSS 19.0 J statistical software (SPSS Japan Inc., Tokyo, Japan). \(P \leq 0.05\) was considered to be statistically significant.

Table 1 shows participants’ characteristics and medical diagnoses. Of the 200 patients included in this study, 120 were allocated to the walking non-independence group and 80 were allocated to the walking independence group. The mean age of subjects was 66.7 years, and 44.5% were men. The diagnoses were connective tissue disease (31.0%), hematologic disease (21.5%), kidney disease (21.5%), digestive disease (9.5%), endocrine metabolic disease (7.0%), respiratory disease (4.0%), liver disease (3.0%), gallbladder disease (1.0%), pancreatic disease (0.5%), urologic disease (0.5%), and gynecologic disease (0.5%). The disease duration was not recorded.

Table 2 shows the results of the univariate analysis. Among the patient characteristics, the only difference identified was that the mean age of the walking non-independence group was significantly older than that of the walking independence group. Among the variables for physical function, the groups differed in the SLR repetition count and the OLST. Among the variables for cognitive function, the groups differed with regard to the orientation score, cautions and calculation score, and reproduction score of the MMSE. Analysis of the laboratory data showed that the walking non-independence and walking independence groups differed with regard to the levels of TP, Alb, RBC, and Hb.

Table 3 shows the results of logistic regression analysis of the outcome measures related to walking independence. The analysis was performed using 10 items, i.e., age, SLR repetition count, OLST, orientation score, cautions and calculation score, reproduction score, RBC count, TP, Alb, and Hb, all of which showed significant differences in the univariate analysis. The SLR repetition count, OLST, the MMSE score for orientation, and the Hb level were selected for inclusion in the crude multivariate model.

In the adjusted model, the following three parameters were associated with the probability of being independent in walking: SLR repetition count (OR=1.310, 95% CI: 1.096–1.565), OLST (OR=2.614, 95% CI: 1.620–4.219), and the MMSE orientation score (OR=2.555, 95% CI: 1.153–5.658). Higher
values of these three parameters meant an increased probability of being independent in walking. In the crude model, a higher Hb (g/dL) level was associated with an increased probability of being independent in walking (OR=1.542, 95% CI: 1.023–2.326); however, the level of significance was not reached in the adjusted model (OR=1.238, 95% CI: 0.765–2.002).

Figure 1 shows the ROC curves, and Table 4 shows the cut-off values, sensitivity, specificity, and AUC obtained from the ROC curve analysis. The cut-off values for each item were as follows: SLR repetition count, 27; maximum OLST, 3.6 s; and orientation score of the MMSE, 9/10 points. The AUC was higher in the order of the OLST (0.974), the SLR repetition count (0.821), and the MMSE orientation score (0.751).

**DISCUSSION**

Our study findings suggest that the SLR repetition count, the OLST, and the MMSE orientation score are simple outcome measures related to walking independence in inpatients with a medical disease in acute care hospitals. The cut-off values for each outcome measure were 27 for the SLR repetition count, 3.6 s for the OLST, and 9/10 for the MMSE
The SLR repetition count was used as an index of muscle strength in this study. As an objective test of lower extremity muscle strength, a manual myometer, such as a handheld dynamometer, is often used. The association between lower limb muscle strength according to a handheld dynamometer and the walking ability has been previously reported, and when the lower limb muscle strength is below a certain level, walking ability is impaired. However, not all clinical facilities have manual myometers. Moreover, specialized knowledge is required to perform the measurement with a manual myometer, and it is difficult for a co-medical non-physiotherapist to perform this measurement. The chair stand 30 s test (CS-30) is an objective evaluation method of lower limb muscle strength that does not use a measuring instrument such as a manual myometer. However, the CS-30 method cannot be performed in frail elderly individuals because its goal is to evaluate rising from a chair with limited support from the upper limbs (i.e., the arms are crossed in front of the chest). It is also difficult for patients in the acute disease phase to continuously stand up from a sitting position for 30 s. In contrast, the SLR is an exercise that uses a simple and feasible leg strength training exercise with the subject lying on a bed. The SLR test can be applied to patients with a wide range of operating capacities, and it is easy to quantify the number of repetitions. In this study,

Table 2. Comparison of patients’ characteristics, physical function, cognitive function, and blood data for the walking non-independence and independence groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Walking non-independence group (n=120)</th>
<th>Walking independence group (n=80)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (male/female)</td>
<td>56/64</td>
<td>35/45</td>
<td>0.587</td>
</tr>
<tr>
<td>Age (years)</td>
<td>68.9 ± 16.8</td>
<td>64.4 ± 16.8</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>19.7 ± 4.1</td>
<td>20.1 ± 4.3</td>
<td>0.822</td>
</tr>
<tr>
<td>Physical function</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLR repetition count</td>
<td>16.2 ± 10.3</td>
<td>27.5 ± 5.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>OLST (s)</td>
<td>1.0 ± 2.1</td>
<td>18.1 ± 11.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cognitive function (MMSE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orientation score</td>
<td>8.0 ± 2.4</td>
<td>9.7 ± 0.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cautions and calculation score</td>
<td>2.4 ± 1.8</td>
<td>4.0 ± 1.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reproduction score</td>
<td>2.2 ± 1.0</td>
<td>2.7 ± 0.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Blood data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total protein (g/dL)</td>
<td>5.6 ± 0.9</td>
<td>6.3 ± 0.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Albumin (g/dL)</td>
<td>2.7 ± 0.6</td>
<td>3.3 ± 0.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Red blood cell (g/dL)</td>
<td>319.8 ± 62.0</td>
<td>364.4 ± 77.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hemoglobin (g/dL)</td>
<td>9.8 ± 1.7</td>
<td>11.1 ± 2.0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

SLR, straight leg raising; OLST, one-leg standing time; MMSE, mini-mental state examination. Data are presented as the mean ± standard deviation.

Table 3. Logistic regression analysis of the outcome measures related to walking independence

<table>
<thead>
<tr>
<th>Variable</th>
<th>Crude model</th>
<th>Adjusted modela</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
</tr>
<tr>
<td>SLR repetition count</td>
<td>1.217**</td>
<td>1.077–1.376</td>
</tr>
<tr>
<td>OLST</td>
<td>2.024**</td>
<td>1.485–2.759</td>
</tr>
<tr>
<td>MMSE orientation score</td>
<td>2.005*</td>
<td>1.066–3.771</td>
</tr>
<tr>
<td>Hb value from the blood test</td>
<td>1.542*</td>
<td>1.023–2.326</td>
</tr>
</tbody>
</table>

aAdjusted for age, sex, body mass index, and diagnosis; *P <0.05, **P <0.01.
Hb, hemoglobin; OR, odds ratio; CI, confidence interval.

orientation score.
The SLR repetition count was used as an index of muscle strength in this study. As an objective test of lower extremity muscle strength, a manual myometer, such as a handheld dynamometer, is often used. The association between lower limb muscle strength according to a handheld dynamometer and the walking ability has been previously reported, and when the lower limb muscle strength is below a certain level, walking ability is impaired. However, not all clinical facilities have manual myometers. Moreover, specialized knowledge is required to perform the measurement with a manual myometer, and it is difficult for a co-medical non-physiotherapist to perform this measurement. The chair stand 30 s test (CS-30) is an objective evaluation method of lower limb muscle strength that does not use a measuring instrument such as a manual myometer. However, the CS-30 method cannot be performed in frail elderly individuals because its goal is to evaluate rising from a chair with limited support from the upper limbs (i.e., the arms are crossed in front of the chest). It is also difficult for patients in the acute disease phase to continuously stand up from a sitting position for 30 s. In contrast, the SLR is an exercise that uses a simple and feasible leg strength training exercise with the subject lying on a bed. The SLR test can be applied to patients with a wide range of operating capacities, and it is easy to quantify the number of repetitions. In this study,
the cut-off value for the SLR repetition count for walking independence was 27, and the discriminating accuracy was high. Measuring the number of SLR repetitions is simple and does not require dedicated equipment. We believe that the SLR repetition count may be used as a simple evaluation of the lower extremity muscle strength in the clinical setting in patients with a medical disease.

The association between OLST and walking ability has been reported.\(^{26}\) Among the balance tests, the OLST is easy to use in acute-phase patients because it is easy to perform and does not require special equipment or a dedicated location for taking the measurements.\(^{34}\) Therefore, the OLST may easily be used as an outcome measure related to walking independence. The cut-off value for the OLST was 3.6 s, and the discriminating accuracy was high. Because previously reported OLST test procedures such as the number of measurements, the endpoint, and the subjects were different,\(^{26}\) a simple comparison with previous studies is difficult. Furthermore, few studies have calculated a cut-off value or have used walking independence as an endpoint. The OLST reflects the lower extremity muscle strength and the function of the foot in terms of ankle control,\(^{35}\) toe strength, and plantar sensation.\(^{36}\) Therefore, the OLST provides a functional evaluation of the entire lower limb, including leg strength and the function of the foot. The OLST had the highest discriminating accuracy among the four items in the logistic regression analysis.

In previous studies, disorientation was reported as a risk for falling.\(^{37}\) In addition, Salgado et al.\(^{38}\) reported that disorientation was associated with a risk for falling according to the MMSE orientation score, and that the MMSE orientation score could be used as a brief assessment of the risk for falling. Reduced cognitive function results in a reduction in posture control; consequently, repeated falls are likely to occur.\(^{39,40}\) In our study, the MMSE orientation score was identified as one of the outcome measures related to walking independence. The cut-off value was 9/10. It was difficult to compare this finding with previous studies because there is no previous report of a cut-off value for the orientation score alone with walking independence as the endpoint. However,
the cut-off score calculated in this study was relatively high. The MMSE score is influenced by age and education history: a low score is associated with an increased age, whereas a high score is associated with an increase in the years of education. Because the patients’ average age in this study was relatively young (66.7 ± 16.9 years), there is a possibility that age affected the MMSE scores. Since education history was not investigated in this study, it is unclear whether education history played a role. Additionally, because the discrimination accuracy of the MMSE orientation score was slightly lower than those of the SLR repetition count and OLST, it is necessary to interpret our findings with care.

It has been reported that lower Hb levels are associated with lower overall body function. Hb is an index that represents anemia. Although the reference value varies depending on the facility, the normal lower limit ranges from 12.7 to 13.7 g/dL in men and from 11.5 to 12.2 g/dL in women. The average Hb level for the walking non-independence group was 9.8 ± 1.7 g/dL, and, consequently, the patients were considered to be anemic. A decrease in the Hb level implies anemia, which means that the transportation of oxygen is insufficient. As a result, a decrease in the Hb level leads to unstable walking. Therefore, we believe that Hb influences walking independence. However, because we found no significant effect of Hb level in the adjusted model, we considered that confounding factors were implicated.

Evaluation not only of physical function but also of cognitive function is important for the prediction of walking independence. Moreover, many existing tests are difficult to use in the acute phase of a disease in inpatients receiving bedside treatment via intravenous drips. The tests identified as relevant in this study included not only physical function but also cognitive function. Moreover, the tests can be used at the bedside for patients with acute disease because they do not require a measuring instrument, a dedicated location for performing the measurements, or a long time to take the measurement. The findings of the present research are, therefore, considered to be of clinical significance.

Study Limitations
There are several limitations to the current study. First, subjects had a variety of medical diseases, and the specificities of the diseases were not considered, even though confounding factors were adjusted for. Fundamentally, it is necessary to examine each diagnosis, because the related factors are different for each diagnosis. Because the selection of subjects was not targeted at inpatients in all internal wards, selection bias was possible. Second, the use of drugs affects the walking ability in those with a medical disease, however, we did not consider the effects of drugs in this study. Third, because the evaluation time (e.g., immediately after the physical therapy intervention or before discharge) was not consistent, there is a possibility that it had an effect on the results. Lastly, since this study had a cross-sectional design, it merely examined the outcome measures related to walking independence. In the future, it will be necessary to verify the validity of the outcome measures identified here in a longitudinal study to determine walking independence in inpatients.

CONCLUSIONS
Our study findings suggest that the SLR repetition count, the OLST, and the MMSE orientation score are simple outcome measures related to the walking independence of inpatients with a medical disease in acute care hospitals. To determine walking independence, it is necessary to evaluate comprehensively the physical function and cognitive function.

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CONFLICTS OF INTEREST
The authors declare that there are no conflicts of interest.

REFERENCES


