History of Falls and Bedriddenness Ranks are Useful Predictive Factors for in-Hospital Falls: A Single-Center Retrospective Observational Study Using the Saga Fall Risk Model

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Introduction: In our former study, we had validated the previously developed predictive model for in-hospital falls (Saga fall risk model) using eight simple factors (age, sex, emergency admission, department of admission, use of hypnotic medications, history of falls, independence of eating, and Bedriddenness ranks [BRs]), proving its high reliability. We found that only admission to the neurosurgery department, history of falls, and BRs had significant relationships with falls. In the present study, we aimed to clarify whether each of these three items had a significant relationship with falls in a different group of patients.

Methods: This was a single-center based, retrospective study in an acute care hospital in a rural city of Japan. We enrolled all inpatients aged 20 years or older admitted from April 2015 to March 2018. We randomly selected patients to fulfill the required sample size. We performed multivariable logistic regression analysis using forced entry on the association between falls and each of the eight items in the Saga fall risk model.

Results: A total of 2932 patients were randomly selected, of whom 95 (3.2%) fell. The median age was 79 years, and 49.9% were men. Multivariable analysis showed that female sex (odds ratio [OR] 0.6, 95% confidence interval [CI] 0.39–0.93, p = 0.022), having a history of falls (OR 1.9, 95% CI 1.16–2.99, p = 0.010), requiring help with eating (OR 1.9, 95% CI 1.12–3.35, p = 0.019), BR of A (OR 6.6, 95% CI 2.82–15.30, p < 0.001), BR of B (OR 7.5, 95% CI 2.95–19.06, p < 0.001), and BR of C (OR 4.1, 95% CI 1.53–11.04, p = 0.005) were significantly associated with falls.

Conclusion: History of falls and BRs were independently associated with in-hospital falls.

Keywords: bedridden, Bedriddenness ranks, fall, predictive model, validation, Saga fall risk model

Introduction

Inpatient falls are a serious problem in the medical health care setting. Various incidences of inpatient falls have been reported, such as 4.24 falls per 1000 patient-days in orthopedic wards in the United States, 3.38 falls per 1000 patient-days in acute care hospitals in the United States, and 2.45 falls per 1000 patient-days in acute care hospitals in Japan, probably owing to the different settings of the studies. Falls in the hospital could mean the patient requires additional examinations and treatments for trauma, delayed discharge, and consequent increase medical costs. Additionally, fall-related trauma and its sequelae can decrease activities of daily living (ADLs), making previously independent people among those needing greater attention or partial or full nursing care in their daily life. Fear of falling and the need for additional care to prevent falls during hospitalization increases the psychological and physical burden on both patients and medical staff. Further increases...
in medical costs owing to falls is a serious problem in Japan, the most super-aged country in the world and with a rapidly aging society, as well as in other aging societies, especially in developed countries.\textsuperscript{10}

Various factors are reported to be associated with falls. Both individual factors of the patient such as impairment of balance and gait, muscle weakness, or inability to follow the instructions of the health care worker, and environmental factors affecting the patient such as slippery floors were included as representative fall-associated factors.\textsuperscript{11} To prevent falls, various methods have been proposed such as creating a favorable environment (eg, placing the nurse call device close to the patient and keeping the floor dry), staff monitoring of patients’ behavior, and education of the patient and medical staff.\textsuperscript{11,12} However, it is not feasible or practical to implement methods to prevent falls for all inpatients owing to the excessive amount of time, cost, and effort required on the part of medical staff. Therefore, detecting patients with a high risk of falls using predictive models is essential for implementing targeted preventive measures, which can reduce health care costs and the number of patients requiring nursing care owing to the sequelae of falls.\textsuperscript{13}

We previously developed and reported two new, easy-to-use predictive models for in-hospital falls, called the Saga fall risk models (SFRMs).\textsuperscript{14} As previously reported, our models, particularly SFRM-2 (S1 Appendix), use only simple parameters that are available on admission, including the official Japanese ADL scale and the Bedriddenness ranks (BRs) of the Ministry of Health, Labour and Welfare (MHLW). Thus, our models differ from previously reported predictive models of falls requiring various complex assessments.\textsuperscript{15,16} BRs are a simple ADL scale widely used in Japanese medical and nursing care settings, which can be assessed with only a few items on a questionnaire.\textsuperscript{17} However, the usefulness of BRs in predicting falls has not been adequately evaluated. We subsequently validated the SFRM-2 in a prospective study using inpatients at two hospitals, an acute care and a chronic care hospital.\textsuperscript{18} The model showed good validity and usefulness.\textsuperscript{18} Our validation study of the SFRM-2 indicated that only admission to the department of neurosurgery, a history of falls, and BRs were significantly associated with in-hospital falls,\textsuperscript{18} which was markedly different from the results of our study in which we developed the predictive models, which showed that seven factors used in the model were significant, except age.\textsuperscript{14} Our previous studies revealed different results for the association between each factor and falls, which might be caused by different backgrounds of the study populations (ie, degree of cognitive impairment, age, primary illness on admission, and type of hypnotic medications prescribed) as well as different study periods.\textsuperscript{14,18} Among those factors, our studies indicated the significance of BRs whereas other previous studies have also shown permanent residual damage from a previous stroke or a history of falls as factors associated with falls.\textsuperscript{14,18–21} Revealing the association between BRs and falls will highlight the usefulness of BRs in predicting falls, which may lead to developing a better and more accurate approach for predicting falls using BRs. However, we performed stratified analyses on patients who had some items not used in the SFRM-2 in our former validation study. Our results showed good discrimination for patients with surgical operations, those without rehabilitation or visual impairment, patients with a length of hospital stay shorter than 10 days, or patients with a Cognitive function score (CFS) of M, defined as severe psychological symptoms, troubled behaviors, or severe physical disorders requiring specialized medical service.\textsuperscript{18,19} However, usefulness of the SFRM-2 in those patients remains to be confirmed owing to the lack of an external validation study.

Because two of our previous studies showed differing results, in the present study, we aimed to clarify the association between inpatient falls and admission to the department of neurosurgery, BRs, and a history of falls in external validation.\textsuperscript{18} Therefore, in the present study, we put forth the hypothesis that BRs, history of falls, or admission to the department of neurosurgery were associated with in-hospital falls. Additionally, we sought to identify those patients in whom use of the SFRM-2 was most suitable, using stratified analysis with some items that were not used in the model: patients with surgical operations, those without rehabilitation or visual impairment, patients with a length of hospital stay shorter than 10 days, and a CFS of M.

**Materials and Methods**

**Study Design, Setting, Participants, and Sample Size**

This was a single-center-based retrospective observational study. We included all inpatients aged 20 years or older admitted to an acute care hospital in a rural city of Japan (Yuai-Kai Foundation and Oda Hospital) (S2 Appendix) between April 2015 and March 2018. The study periods were completely different between the present study and our
previous studies. Additionally, data collection periods were delimited by the date of patient admission, and thus duplicate data were not included. Patients younger than 20 years old or those without the data of BRs were excluded. In this study, each hospitalization of a patient was counted as one case. As a result, each hospitalization of the same patient was counted as a separate case. We calculated the sample size for the multivariate analysis using eight covariates, which showed a required sample size of 120 cases of fall. Then, we performed random sampling based on the expected fall rate of 4%.\textsuperscript{14,18} Patients were divided into two groups, those who had experienced a fall during hospitalization (Fall Group) and who had not experienced a fall (non-Fall Group).

Data
The data in this study were extracted from electronic medical records or the hospital’s health records. The extracted variables included the following: date of admission, age,\textsuperscript{22,23} sex (male or female),\textsuperscript{14,22} department of admission (internal medicine, neurosurgery, or other), emergency admission (present or absent), independence of eating (independent, requiring assistance), BRs and CFS according to the MHLW of Japan,\textsuperscript{17,19} use of hypnotic medications (either benzodiazepine or non-benzodiazepine types: present or absent),\textsuperscript{22} a referral letter written by a primary physician outside of Oda Hospital who saw a patient before admission (present or absent), visual impairment (present or absent),\textsuperscript{22} a past history of falls (present or absent),\textsuperscript{20,24} and parkinsonism (present or absent).\textsuperscript{25,26} Additionally, information on developments during hospitalization regarding surgical operations (present or absent), rehabilitation (present or absent), in-hospital falls (present or absent), and the date of discharge were also extracted.

BRs, use of hypnotic medications, and a history of falls were routinely evaluated by nurses belonging to the hospital within 72 hours from admission and were recorded in the electronic medical record. BRs and CFS are official scales of ADLs in Japan and are widely used in medical and long-term care systems. The BRs are classified into five broad categories or nine detailed categories, and the CFS is classified into six categories or eight detailed categories.\textsuperscript{17,19} In this study, BRs were assessed using five categories (normal, J: independence/autonomy, A: housebound, B: chair-bound, or C: bed-bound) and the CFS in six categories (normal, I: almost independent, II: independent with slight difficulty, III: dependent, IV: dependent and requiring constant care, and M). As in our previous studies, both benzodiazepines and non-benzodiazepines were included among hypnotic medications, except for melatonin receptor agonists and orexin receptor antagonists because these drugs have fewer side effects that cause falls.\textsuperscript{27,28} If an inpatient experiences a fall, a nurse in charge of the patient or who finds the patient completes an incident/accident report. The number of falls was calculated using these reports. Only data of the first fall in the hospital during the hospitalization were collected. Fall was defined as any unexpected fall from any height or position, including a fall from stairs, a chair, bed, walking, sitting, or lying down, irrespective of any injury associated with the fall. Length of hospital stay was calculated using the dates of admission and discharge.

Statistical Analysis
For each patient in the population overall, those in the Fall Group, and those in the non-Fall Group, continuous and categorical variables are presented as median (interquartile range) and absolute number (percentage), respectively. We calculated p values using the Mann–Whitney U-test for continuous variables and chi-squared test for categorical variables. All continuous variables were evaluated using the Mann–Whitney U-test because these had a non-normal distribution. A multiplicity of tests was not adjusted in the exploratory analysis. Multivariable logistic regression analysis with forced entry was performed using all items included in the SFRM-2, which was the simpler model of our two newly developed models, with fewer assessment items (age, sex, emergency admission, department of admission, use of hypnotic medications, past history of falls, independence of eating as an assessment item of the Barthel index, and BRs).\textsuperscript{14} We used the same multivariable analysis methods as those used in previous studies.\textsuperscript{18} For stratified analyses, we selected items with area under the receiver operating characteristic curve (AUC) > 0.8 in our previous validation study, other than the eight items used in the SFRM-2.\textsuperscript{18} We compared the AUC and 95% confidence interval (CI) between two groups, those with or without surgical operations, rehabilitation during hospitalization, visual impairment, or a hospital stay shorter than 10 days, and among six groups with each CFS score (normal, I, II, III, IV, and M). As a secondary evaluation, we calculated the SFRM-2 score of each patient to assess predictive performance of the SFRM-2 by...
calculating the AUC, 95% CI, and shrinkage coefficient. Analyses were performed using IBM SPSS version 27 (IBM Corp., Armonk, NY, USA).

**Ethical Considerations**
This study is in line with the Declaration of Helsinki and the ethical guidelines for medical and health research involving human subjects issued by the MHLW and the Ministry of Education, Culture, Sports, Science, and Technology in Japan. This study was approved by the research ethics committee of the Yuai-Kai Foundation and Oda Hospital (No. 20180630). The study was registered at the University Hospital Medical Information Network (UMIN) at [www.umin.ac.jp](http://www.umin.ac.jp) (UMIN ID: UMIN000047453). We obtained consent from all patients via the comprehensive agreement method of the hospital, and the anonymity of patients was protected.

**Results**

** Patients' Background and Incidence of Fall Events**
During the study period, among overall 9344 inpatients, 312 patients aged younger than 20 years and 1337 with missing data of BRs were excluded. As a result, a total of 7695 adult patients were eligible, 271 (3.5%) of whom had a fall while in the hospital (Figure 1). There were 41 (15%) from a total of 271 falls with some kind of injury owing to fall, with or without permanent sequelae. Random sampling was conducted to meet the required sample size, and 2932 patients were thus included in the analysis. The median age (interquartile range) was 79 (68–86) years, and the median length of hospital stay (interquartile range) was 10 (5–18) days (Table 1). A total of 95 falls occurred (3.2%). The incidence rate of falls was 2.18 per 1000 patient-days. A total of 1337 patients with missing BR data were excluded. Those patients had a median age of 57 years (44–65), 54.4% were men, and only four among them (0.3%) had a fall.

**Univariate Analysis**
The results of univariate analysis are shown in Table 1. Patients in the Fall Group were significantly older (83 years, 95% CI: 76–89 vs 79 years, 95% CI: 68–86, p = 0.001) and had a significantly longer hospital stay (27 days, 95% CI: 17–46

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**Figure 1** Data flow diagram. A total of 7695 adult participants were eligible. Random sampling was conducted to fulfill the required sample size. Consequently, 2932 patients were included in the analysis, 95 of whom experienced in-hospital fall.
This group was also more likely to have an admission to the department of internal medicine or neurosurgery (64.2% vs 48.0%, 6.3% vs 3.2%, p = 0.001), to have an emergency admission (41.1% vs 27.6%, p = 0.001), a history of falls (33.7% vs 11.4%, p < 0.001), and rehabilitation during hospitalization (84.2% vs 45.4%, p < 0.001), and were less likely to be able to eat independently (36.8% vs 70.7%, p < 0.001). The proportions of patients with a BR of A, B, and C and patients with CFS of I, II, III, and IV were significantly greater in the Fall Group, with significantly different distributions between the two groups.

Table 1: Characteristics of Patients and the Results of Univariate Analysis

<table>
<thead>
<tr>
<th>Variable, Category</th>
<th>All Patients n = 2932</th>
<th>Fall Group n = 95</th>
<th>Non-Fall Group n = 2837</th>
<th>p value&lt;sup&gt;†&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>79 (68–86)</td>
<td>83 (76–89)</td>
<td>79 (68–86)</td>
<td>0.001</td>
</tr>
<tr>
<td>Sex, Male</td>
<td>1463 (49.9%)</td>
<td>55 (57.9%)</td>
<td>1408 (49.6%)</td>
<td>0.119</td>
</tr>
<tr>
<td>Emergency admission, Yes</td>
<td>823 (28.1%)</td>
<td>39 (41.1%)</td>
<td>784 (27.6%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Referral letter, Presence</td>
<td>789 (26.9%)</td>
<td>34 (35.8%)</td>
<td>755 (26.6%)</td>
<td>0.059</td>
</tr>
<tr>
<td>Department, Internal Medicine</td>
<td>1423 (48.5%)</td>
<td>61 (64.2%)</td>
<td>1362 (48.0%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Department, Neurosurgery</td>
<td>96 (3.3%)</td>
<td>6 (6.3%)</td>
<td>90 (3.2%)</td>
<td></td>
</tr>
<tr>
<td>Hypnotic medications, Using</td>
<td>370 (12.6%)</td>
<td>16 (16.8%)</td>
<td>354 (12.5%)</td>
<td>0.270</td>
</tr>
<tr>
<td>Hypnotic medications, Missing</td>
<td>171 (5.8%)</td>
<td>3 (3.2%)</td>
<td>168 (5.9%)</td>
<td></td>
</tr>
<tr>
<td>Parkinson’s syndrome, Presence</td>
<td>27 (0.9%)</td>
<td>2 (2.1%)</td>
<td>25 (0.9%)</td>
<td>0.217</td>
</tr>
<tr>
<td>History of falls, Presence</td>
<td>355 (12.1%)</td>
<td>32 (33.7%)</td>
<td>323 (11.4%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Visual impairment, Presence</td>
<td>40 (1.4%)</td>
<td>2 (2.1%)</td>
<td>38 (1.3%)</td>
<td>0.682</td>
</tr>
<tr>
<td>Eating, Independent</td>
<td>2040 (69.6%)</td>
<td>35 (36.8%)</td>
<td>2005 (70.7%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Eating, Requiring assistance</td>
<td>891 (30.4%)</td>
<td>60 (63.2%)</td>
<td>831 (29.3%)</td>
<td></td>
</tr>
<tr>
<td>Eating, Missing category</td>
<td>1 (0.0%)</td>
<td>0 (0.0%)</td>
<td>1 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Bedriddenness rank, Normal</td>
<td>1275 (43.5%)</td>
<td>9 (9.5%)</td>
<td>1266 (44.6%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Bedriddenness rank, J</td>
<td>294 (10.0%)</td>
<td>4 (4.2%)</td>
<td>290 (10.2%)</td>
<td></td>
</tr>
<tr>
<td>Bedriddenness rank, A</td>
<td>528 (18.0%)</td>
<td>30 (31.6%)</td>
<td>498 (17.6%)</td>
<td></td>
</tr>
<tr>
<td>Bedriddenness rank, B</td>
<td>330 (11.3%)</td>
<td>28 (29.5%)</td>
<td>302 (10.6%)</td>
<td></td>
</tr>
<tr>
<td>Bedriddenness rank, C</td>
<td>505 (17.2%)</td>
<td>24 (25.3%)</td>
<td>481 (17.0%)</td>
<td></td>
</tr>
<tr>
<td>Cognitive function score, Normal</td>
<td>1778 (60.6%)</td>
<td>35 (36.8%)</td>
<td>1743 (61.4%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Cognitive function score, I</td>
<td>336 (11.5%)</td>
<td>16 (16.8%)</td>
<td>320 (11.3%)</td>
<td></td>
</tr>
<tr>
<td>Cognitive function score, II</td>
<td>240 (8.2%)</td>
<td>12 (12.6%)</td>
<td>228 (8.0%)</td>
<td></td>
</tr>
<tr>
<td>Cognitive function score, III</td>
<td>424 (14.5%)</td>
<td>23 (24.2%)</td>
<td>401 (14.1%)</td>
<td></td>
</tr>
<tr>
<td>Cognitive function score, IV</td>
<td>114 (3.9%)</td>
<td>8 (8.4%)</td>
<td>106 (3.7%)</td>
<td></td>
</tr>
<tr>
<td>Cognitive function score, M</td>
<td>32 (1.1%)</td>
<td>1 (1.1%)</td>
<td>31 (1.1%)</td>
<td></td>
</tr>
<tr>
<td>Surgical operation, Undergone</td>
<td>956 (32.6%)</td>
<td>25 (26.3%)</td>
<td>931 (32.8%)</td>
<td>0.221</td>
</tr>
<tr>
<td>Rehabilitation, Undergone</td>
<td>1367 (46.6%)</td>
<td>80 (84.2%)</td>
<td>1287 (45.4%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Length of hospital stay (days)</td>
<td>10 (5–18)</td>
<td>27 (17–46)</td>
<td>10 (5–17)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Notes: <sup>†</sup>p values were calculated by Mann-Whitney U-test for continuous variables and chi-squared test for categorical variables. Continuous and categorical variables are shown as median value (interquartile range) and number (percent). Bedriddenness ranks: J, independence/autonomy; A, house-bound; B, chair-bound; C, bed-bound. Cognitive function scores: I, almost independent in daily living with only slight cognitive impairment; II, independent with slight difficulty in daily living or communication under careful overseeing; III, dependent in daily living or communication; IV, dependent in daily living or communication, and requires constant care; M, severe psychological symptoms, troubled behaviors or severe physical disorders requiring specialized medical service.

This group was also more likely to have an admission to the department of internal medicine or neurosurgery (64.2% vs 48.0%, 6.3% vs 3.2%, p = 0.001), to have an emergency admission (41.1% vs 27.6%, p = 0.005), a history of falls (33.7% vs 11.4%, p < 0.001), and rehabilitation during hospitalization (84.2% vs 45.4%, p < 0.001), and were less likely to be able to eat independently (36.8% vs 70.7%, p < 0.001). The proportions of patients with a BR of A, B, and C and patients with CFS of I, II, III, and IV were significantly greater in the Fall Group, with significantly different distributions between the two groups.
Multivariable Analysis

Multivariable logistic regression analysis showed a significant relationship between falls and being a male, having a history of falls, requiring eating assistance, and BRs (Table 2). The odds ratio (OR) for female sex was 0.6 (95% CI 0.39–0.93, p = 0.022), admission to the department of neurosurgery 1.8 (95% CI 0.70–4.69, p = 0.219), having a history of falls 1.9 (95% CI 1.16–2.99, p = 0.010), requiring eating assistance 1.9 (95% CI 1.12–3.35, p = 0.019), and a BR of J 2.0 (95% CI 0.60–6.81, p = 0.258), A 6.6 (95% CI 2.82–15.30, p < 0.001), B 7.5 (95% CI 2.95–19.06, p < 0.001), and C 4.1 (95% CI 1.53–11.04, p = 0.005).

Performance of Predictive Models

The AUC for the performance of SFRM-2 was 0.741 (95% CI: 0.700–0.783) (S1 Figure). The incidence of falls that were observed was consistent with the predicted incidence calculated using the SFRM-2, with a shrinkage coefficient of 0.922 (S2 Figure).

Stratified Analysis

In the stratified analysis, the AUC of the SFRM-2 was 0.840 (95% CI: 0.790–0.891) for the group who underwent surgery, 0.695 (95% CI: 0.640–0.750) without surgery, 0.642 (95% CI: 0.584–0.700) with rehabilitation, 0.803 (95% CI: 0.729–0.877) without rehabilitation, 0.814 (95% CI: 0.766–0.862) with a CFS of normal, 0.736 (95% CI: 0.608–0.863) with CFS of I, 0.506 (95% CI: 0.337–0.675) with CFS of II, 0.555 (95% CI: 0.417–0.694) with CFS of III, 0.711 (95% CI: 0.539–0.883) with CFS of IV, 0.968 (95% CI: 0.906–1.000) with CFS of M, 1.000 (95% CI: 1.000–1.000) with visual impairment, 0.737 (95% CI: 0.696–0.778) without visual impairment, 0.654 (95% CI: 0.600–0.708) with hospital stay ≥ 10 days, and 0.826 (95% CI: 0.725–0.927) with hospital stay < 10 days (Figure 2).

Discussion

In the present study, we found that only two items, each category of BRs and having a history of falls, were significantly associated with in-hospital falls. The results of our first study, in which we developed the model, showed significance for seven items used in the model, apart from age.14 Our second study, in which we had validated the prediction model for

<table>
<thead>
<tr>
<th>Variable, Category (Reference)</th>
<th>OR</th>
<th>95% CI</th>
<th>p value‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.0</td>
<td>0.97–1.01</td>
<td>0.211</td>
</tr>
<tr>
<td>Sex, Female (Male)</td>
<td>0.6</td>
<td>0.39–0.93</td>
<td>0.022</td>
</tr>
<tr>
<td>Emergency admission, Presence (Absence)</td>
<td>1.2</td>
<td>0.75–1.80</td>
<td>0.500</td>
</tr>
<tr>
<td>Department, Internal Medicine (Others)</td>
<td>1.3</td>
<td>0.82–2.15</td>
<td>0.246</td>
</tr>
<tr>
<td>Department, Neurosurgery (Others)</td>
<td>1.8</td>
<td>0.70–4.69</td>
<td>0.219</td>
</tr>
<tr>
<td>Hypnotic medications, Using (Not using)</td>
<td>1.1</td>
<td>0.61–1.90</td>
<td>0.804</td>
</tr>
<tr>
<td>Hypnotic medications, Missing (Not using)</td>
<td>0.4</td>
<td>0.12–1.29</td>
<td>0.122</td>
</tr>
<tr>
<td>History of falls, Presence (Absence)</td>
<td>1.9</td>
<td>1.16–2.99</td>
<td>0.010</td>
</tr>
<tr>
<td>Eating, Requiring assistance (Independent)</td>
<td>1.9</td>
<td>1.12–3.35</td>
<td>0.019</td>
</tr>
<tr>
<td>Bedriddenness rank, J (Normal)</td>
<td>2.0</td>
<td>0.60–6.81</td>
<td>0.258</td>
</tr>
<tr>
<td>Bedriddenness rank, A (Normal)</td>
<td>6.6</td>
<td>2.82–15.30</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Bedriddenness rank, B (Normal)</td>
<td>7.5</td>
<td>2.95–19.06</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Bedriddenness rank, C (Normal)</td>
<td>4.1</td>
<td>1.53–11.04</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Notes: Bedriddenness ranks: J, independence/autonomy; A, house-bound; B, chair-bound; C, bed-bound. ‡p values for Wald test.

Abbreviations: OR, odds ratio; 95% CI, 95% confidence interval.
falls, revealed that three factors were significantly related to falls: admission to the department of neurosurgery, BRs, and a history of falls. We conducted the present study to confirm the significance of the three above items in a different set of patients. Additionally, we conducted stratified analysis of items other than the eight items used in the model to identify suitable groups for use of the SFRM-2. The findings showed that the AUC of the model was 0.74 or higher in patients undergoing surgery, those without rehabilitation, patients with a CFS of normal, and those with a hospital stay < 10 days. The AUC was less than 0.74 in patients who did not undergo surgery; had rehabilitation; had a CFS of I, II, and III; and those with a hospital stay ≥ 10 days.

Multivariable analysis in this study showed that each category of BRs and having a history of falls, male sex, and requiring eating assistance were significantly associated with falls. These results clarified that in all three of our studies, BRs and history of fall were significantly associated with in-hospital falls. Therefore, it is appropriate to conclude that BRs are a truly useful item related to predicting the risk of falls. BRs are an official Japanese ADL scale that is widely used in long-term care and health care systems in Japan, with a simple assessment process involving only a few steps. BRs are also reported to be highly related to ADLs, including in the evaluation of whether a person can move around outside of bed alone or turn over in bed unassisted or whether assistance is required in ADLs such as eating, dressing, or toileting. Because ADLs and falls are reported to be strongly related, the relationship between BRs and falls is reasonable. Considering the highest ORs was for BRs among all the other items revealed in the multivariable analyses, BRs are highly beneficial for predicting in-hospital falls. A history of falls has been previously reported to be a factor associated with falls. Patients with such a history are likely to have many risk factors for falls, such as muscle weakness in the extremities, impaired balance, or a tendency to wander owing to dementia.

Figure 2: Results of stratified analyses.
Abbreviation: AUC, area under the receiver operating characteristic curve.
The findings of the present study failed to show a significant relationship of admission to the department of neurosurgery with falls, which was found in our two previous studies.\textsuperscript{14,18} Neurosurgery inpatients had a higher proportion of BRs and CFS of normal, and lower proportions of BRs of A and B, than patients in the Fall Group (S1 Table). These facts suggested that more patients admitted to the department of neurosurgery had normal cognitive function and ADLs than those with dementia or impaired ADLs who naturally have a higher risk of falls, making the former group of patients less likely to experience a fall.\textsuperscript{19,32,33,37,38} Additionally, the percentage of patients admitted to the department of neurosurgery who were undergoing rehabilitation during hospitalization was lower than that of patients in the Fall Group (57.3\% vs 84.2\%). Patients undergoing rehabilitation in acute care hospitals could be more prone to falls owing to disability or more frequent opportunities to fall owing to a high motivation to exercise.\textsuperscript{39} Taken together, a smaller number of patients with impairment of ADLs or cognitive impairments or who were undergoing rehabilitation might have led to the lower fall rate, subsequently leading to a failure to show significance in this group of patients.

Stratified analyses in this study were conducted to identify those populations in whom use of the SFRM-2 was most suitable. The results showed that patients who underwent surgical operations, those without rehabilitation, with normal CFS, and with a hospital stay < 10 days had an AUC of 0.74 or higher. Surgical operation is reported to have a negative relationship with falls because many surgical patients are fit enough to undergo surgery, are independent in terms of ADLs,\textsuperscript{33,40} or have restricted their activity after surgery during recuperation, which could reduce the opportunity to experience a fall after surgical operation.\textsuperscript{40} The group without rehabilitation had a larger proportion of patients with factors that lower the risk for falls such as independence in ADLs and no emergency admission, in comparison with overall patients or those undergoing rehabilitation (S2 Table). Such higher negative predictive value for predicting patients with a low risk for falls would be highly useful to allocate health care resources toward other more suitable patients. The SFRM-2 was also shown to be valuable for the group of patients with normal CFS. These patients only had a 1.97\% fall rate. Patients with normal CFS are naturally considered to be less prone to falling. The SFRM-2 was also shown to be suitable for patients with a hospital stay < 10 days because the model evaluation was conducted very close to the time of admission. A long hospital stay can itself cause a decline in ADLs or cognitive functions and has been reported as a factor associated with falls.\textsuperscript{41–43} The SFRM-2 is more accurate for patients with a shorter hospital stay because the results of the model evaluation performed on admission are less likely to change during hospitalization. Therefore, it might be recommended that use of the SFRM-2 be restricted to an acute medical setting or that another evaluation study be conducted in a chronic setting.

The AUC and shrinkage coefficient of SFRM-2 in this study were excellent, which means the SFRM-2 is a reliable and valuable model. Although various fall prediction models are already available, such as the Morse Fall Scale, St Thomas Risk Assessment Tool in Falling Elderly Inpatients, or Hendrich II Fall Risk Model, these are very complicated, difficult, and time-consuming to evaluate.\textsuperscript{44} Despite fewer items being included in those models, the SFRM-2 is much more convenient for patient evaluation on admission. Furthermore, the SFRM-2 is unique in that it includes BRs, which have been used nationwide in Japan.

**Limitations**

There were several limitations in this prospective study. Although the period of data collection differed among patients, participants in the present study were inpatients at the same hospital as that in our previous studies, which might have led to selection bias because of similarities in characteristics of the population. Therefore, conducting multicenter validation studies with different populations in various medical settings including high-level medical institutions and chronic care hospitals is ideal. We excluded a group of patients with missing BRs data from the present analysis. Many of these patients had nearly normal ADLs and were less likely to fall, which may have affected the results of the present study. The stratified analysis included items with only a few samples, which could yield unreliable results. Finally, in this study, we failed to evaluate interventions to prevent in-hospital falls, which might have affected the results.

**Conclusion**

The BRs and a history of falls could be useful predictive factors of in-hospital falls, with independent associations according to our study findings. Additionally, our predictive model of falls, the SFRM-2, could be more suitable for use...
in patients undergoing surgical operations, those without rehabilitation, patients with normal CFS, and those with a hospital stay < 10 days, in whom the model has greater discriminative ability.

Abbreviations
ADLs, activities of daily living; AUC, area under the receiver operating characteristic curve; BR, Bedriddenness rank; CFS, Cognitive function score; CI, confidence interval; MHLW, Ministry of Health, Labour and Welfare; OR, odds ratio; SFRM-2, Saga fall risk model 2.

Data Sharing Statement
The datasets generated and analyzed during the current study are available in the UMIN-ICDR repository, https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000054074.

Ethics Approval and Informed Consent
This study conforms to the Ethical Guidelines for Medical and Health Research Involving Human Subjects issued by the Japanese MHLW and the Ministry of Education, Culture, Sports, Science, and Technology. This study was approved by the research ethics committee of the Yuai-Kai Foundation and Oda Hospital (No. 20180630). We obtained consent from all patients using the hospital’s comprehensive agreement method, and anonymity of patients was protected.

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Author Contributions
All authors made a significant contribution to the work reported with respect to the conception, study design, execution, acquisition of data, analysis, and interpretation. All authors took part in drafting, revising, or critically reviewing the article and gave their final approval of the version submitted for publication. All the authors have agreed on the journal for submission and agree to be accountable for all aspects of the work.

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