Proposal for a New Predictive Scale for Recurrent Risk of Fall in a Cohort of Community-Dwelling Patients with Stroke

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Objectives: This study aimed to determine risk factors related to the occurrence of falls in stroke patients and to propose a new predictive scale for falls. *Methods:* Demographic and clinical data were collected and the following scales were applied: Barthel Index, Timed Up and Go Test (TUG), and National Institutes of Health Stroke Scale (NIHSS). Subjects were followed prospectively for 2 years for the occurrence of recurrent (≥2) falls. Kaplan–Meier curves were constructed and univariable associations were tested using log-rank test. Two separate multivariable models were then used: the first used Cox proportional hazards regression and the second used Poisson regression. In each model, significant associations were considered present with a P value less than .05. *Results:* We evaluated 150 individuals and the final analysis included 131 patients; the average age of the patients was 55.8 ± 13 years, 52% were women, and the median NIHSS score was 2 (interquartile range = 1-5). Falls occurred in 17% of patients, with a median of 23 months of follow-up (interquartile range = 16-26 months). In the multivariable Cox regression model, only TUG quartile, female gender, and posterior circulation territory involvement remained significant predictors of recurrent falls. We used the predictors from the Cox regression model to propose a new recurrent fall risk scale. The area under the receiver operating characteristic curve was 73%, 95% confidence interval = 62%-83%, P = .001, with 81.3% sensitivity and 41.8% specificity. *Conclusions:* The new predictive scale for recurrent risk (including TUG, posterior circulation territory involvement, and female gender) is presented as an instrument for monitoring the risk of recurrent falls. **Key Words:** Stroke—fall predictors—recurrent fall—TUG.

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Introduction

Stroke is a major health problem worldwide and is considered as one of the most important causes of death and disability.[1] The occurrence of falls and its consequences are referred to as one of the most common complications after stroke, and thus the identification of individuals likely to fall becomes an important priority in health care for this population of patients with stroke.[2,3] Factors associated with falls in the acute phase of stroke are not the same as those observed in individuals living in the community, in which balance control is required in performing more complex tasks.[4]

Several studies have aimed at finding demographic and comorbidity risk factors for falls and in which circumstances these falls occur.[5-8] Other studies have conducted clinical tests evaluating gait and balance to prospectively identify individuals at higher risk of falling.[9,10] However, specific validated instruments predicting falls are not widely available for this community-dwelling population of patients with stroke.[11,12]

Longitudinal studies with stroke survivors in different clinical and demographic conditions may enable increased awareness of modifiable and/or treatable factors related to the risk or occurrence of falls, and may also be used to encourage the adoption of preventive measures essential to the maintenance of functional capacity in this population of patients with stroke.[2,13] The present study aimed to determine risk factors related to the occurrence of falls in stroke patients and to propose a new predictive scale for falls.

Methods

Study Design and Population

This is a cohort study wherein the primary outcome was the occurrence of recurrent falls. The cohort was composed of stroke patients who were recruited at the Stroke Clinic of the Federal University of Bahia, Brazil, had clinical and radiological diagnoses of ischemic or hemorrhagic stroke, regardless of the number of events, and presented with the ability to walk independently. The Stroke Clinic receives outpatients referred from stroke units or family health clinics from the public health system in Brazil, to complete investigation of stroke mechanism and to define long-term treatment strategies. Stroke was defined as a focal neurological deficit lasting more than 24 hours, and confirmed by neuroimaging (computed tomography or magnetic resonance imaging).[14]

The ability to walk independently was identified in the initial assessment of each patient, selecting the ones who could walk alone in the outpatient setting, making use or not of orthoses or mobility aids, but without the need of assistance for transfers or during gait.

We excluded patients with other diagnoses, such as those with vestibular disorders, Parkinson's disease, or other neurological or orthopedic diseases that could affect balance. We also excluded individuals unable to understand test instructions or perform the requested tasks due to cognitive deficits (comprehension aphasia or dementia) based on a formal evaluation by a board-certified neurologist.

Data Collection Procedure

Consecutive patients were enrolled by completing a questionnaire containing information on demographic and clinical data such as age, gender, affected brain hemisphere, time from last stroke until admission to study, medications, vascular territory, use of orthoses or assistive devices, and previous history of falls. To minimize recall bias, we considered as previous history of falls the ones that occurred during the last year.

The National Institutes of Health Stroke Scale (NIHSS) was used to assess the severity of stroke,[15] the modified Barthel Index to assess functional capacity/daily life activities,[15,16] the European Quality of Life-5 Dimensions (EQ-5D) to assess quality of life,[17] and the Timed Up and Go Test (TUG) to evaluate functional mobility.[12] These scales were all applied on the day of study recruitment.

The TUG quantifies the time in seconds it takes for the individual to rise from a standardized chair, walk 3 m, and sit back. The individual is instructed to walk at his or her usual pace, with or without the use of orthoses.[18] The TUG was divided into quartiles, based on previous data linking TUG as a predictor of falls.[10,12,19]

Upon enrollment into the cohort, the subjects were followed prospectively for 2 years for the occurrence of recurrent (≥2) falls over the study period, the primary outcome of the present study. We chose recurrent falling as the primary outcome based on previous data suggesting that a single fall may be accidental and may not be as clinically relevant as 2 or more falls.[20] Secondary outcomes during follow-up included death, stroke, and new bone fractures. During follow-up, data were collected quarterly in clinical reassessment at the Stroke Clinic or by telephone. In case of patient incapacity to respond to the call, the patients' caregivers were interviewed. The examiners responsible for follow-up remained blinded to the patient's initial assessment data. To avoid recall bias and information loss, all patients and caregivers received a diary for recording falls. This project was approved by the local ethics committee and all individuals or caregivers participating in the study signed a consent form.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences version 17.0 (SPSS Inc., Chicago, IL). Descriptive statistics included means and standard deviations for normally distributed continuous variables; median and interquartile range for non-normally distributed continuous variables; and proportions for categorical variables. Kaplan–Meier curves were constructed relating each categorical predictor to the time-dependent variable of recurrent falls, defined as 2 or more falls during the study period, and univariable associations were tested using log-rank tests. For model building, we used independent variables with a possible association to recurrent falls ($P < .20$) as well as variables not necessarily demonstrating statistical significance, but referred to in the literature as being associated with the occurrence of falls. Two separate multivariable models were then used: the first used Cox proportional hazards regression to test the association between these predictors and recurrent falls as a binary outcome. The second

model used Poisson regression to test the association between each predictor and fall count over time. In each model, significant associations were considered present for any predictor with a *P* value less than .05.

Power was calculated based on previous data from the baseline cohort, where TUG time was the main predictor of falls.[21] With 150 patients, we would have 80% power to detect a hazard ratio of 1.6 or above between patients with TUG times above and below the median.

To build a clinical scale to predict recurrent risk of fall, we used each significant predictor from the Cox proportional hazards model, considering the effect size (beta coefficient) of each predictor as the criterion to attribute a value in discrete points for each predictor, to be added together for the total score. We then constructed a receiver operating characteristic (ROC) curve with the new clinical scale predicting recurrent falls and calculated the area under the ROC curve, as well as sensitivity, specificity, and positive and negative predictive values for each score of the new clinical scale.

Results

We evaluated 150 individuals between March 2009 and September 2010. The median follow-up time was of 23 months (interquartile range = 16-26 months). During follow-up, 19 patients who did not attend appointments at the clinic and could not be contacted by phone were lost to follow-up. There were no significant differences in these 19 patients compared to other patients in relation to the results of NIHSS, TUG, MBI, demographic characteristics, and brain hemisphere or vascular territory affected. The final analysis included 131 patients, and the clinical and demographic characteristics of the stroke patients are described in Table 1. The average age of the study participants was 55.8 years (±13) and 52% were women. None of the patients were chronic alcohol users. The median NIHSS score was 2 points (interquartile range = 1-5), representing mild to moderate deficits. The median time since the last stroke was 13.5 months (interquartile range = 5-35 months) and 52% had some injury in the right hemisphere. The mBI score was 49 points (interquartile range = 47-50), with these individuals being thus classified as moderately dependent to independent, and the median EQ-5D score was .66 (interquartile range .25-.80), representing an impaired quality of life for most patients.

History of falls in the previous year was found in 49 patients (37%). During follow-up, 57 patients (43%) had 1 or more falls and 32 (24%) had 2 or more falls. Most falls occurred at home (56%), in the morning (42%), and while these individuals were walking (60%). Death occurred in 5 patients (3%); there were no recurrent strokes or bone fractures.

Analysis of survival curves showed that the distribution of time between patient entry in the study until the occurrence of recurrent falls differed significantly ($P < .20$) according to gender ($P = .028$), use of vasodilators ($P = .120$), posterior circulation territory ($P = .049$), and TUG quartile ($P = .001$), tested by log-rank test. There was no statistical difference between fallers and nonfallers regarding age, time since stroke, side of injury, severity of stroke, use of auxiliary gear, previous fall, and functional capacity (Fig 1).

In the multivariable Cox regression model, only TUG quartile, female gender, and posterior circulation territory involvement remained significant predictors of falls (Table 2).

The Poisson regression model confirmed the independent association between fall rate and the following variables: high TUG (incidence rate ratio = 7.96, 95% confidence interval = 2.38-26.0, $P = .001$) and posterior circulation involvement (incidence rate ratio = 19.8, 95% confidence interval = 1.85-180.47, $P = .012$). Additionally, female gender (incidence rate ratio = 18.52, 95% confidence interval = 1.47-197.81, $P = .017$) and previous fall (incidence rate ratio = .06, 95% confidence interval = .00-.68,

Table 1. *Demographic and clinical characteristics of 131 stroke patients living in the community and assisted in an outpatient clinic of an educational institution in the city of Salvador, Bahia*

Variables	Total (N = 131)
Age, mean (SD)	55.8 (13.3)
Females, n (%)	68 (52)
Time since stroke in months, median (interquartile range)	13.5 (5-35)
Right hemisphere injury, n (%)	64 (52.5)
Posterior vascular territory injury, n (%)	38 (29)
Medications, n (%)	
Use of vasodilators	22 (17.1)
Use of antihypertensives	107 (81.7)
Use of beta blockers	32 (24.4)
Use of diuretics	50 (38.2)
Use of alpha blockers	2 (1.5)
Use of psychotropic drugs	13 (9.9)
Use of antiepileptic drugs	28 (21.4)
Previous fall, n (%)	49 (37.4)
Severity of stroke (NIHSS score), median (interquartile range)	2 (1-5)
Functional capacity (mBI score), median (interquartile range)	49 (47-50)
Assistive devices, n (%)	19 (14.6)
TUG time (s), median (interquartile range)	15 (12-20)
Quality of life (EQ-5D), median (interquartile range)	.66 (.25-.80)

Abbreviations: EQ-5D, European Quality of Life-5 Dimensions; mBI, modified Barthel Index; NIHSS, National Institutes of Health Stroke Scale; SD, standard deviation; TUG, Timed Up and Go Test.

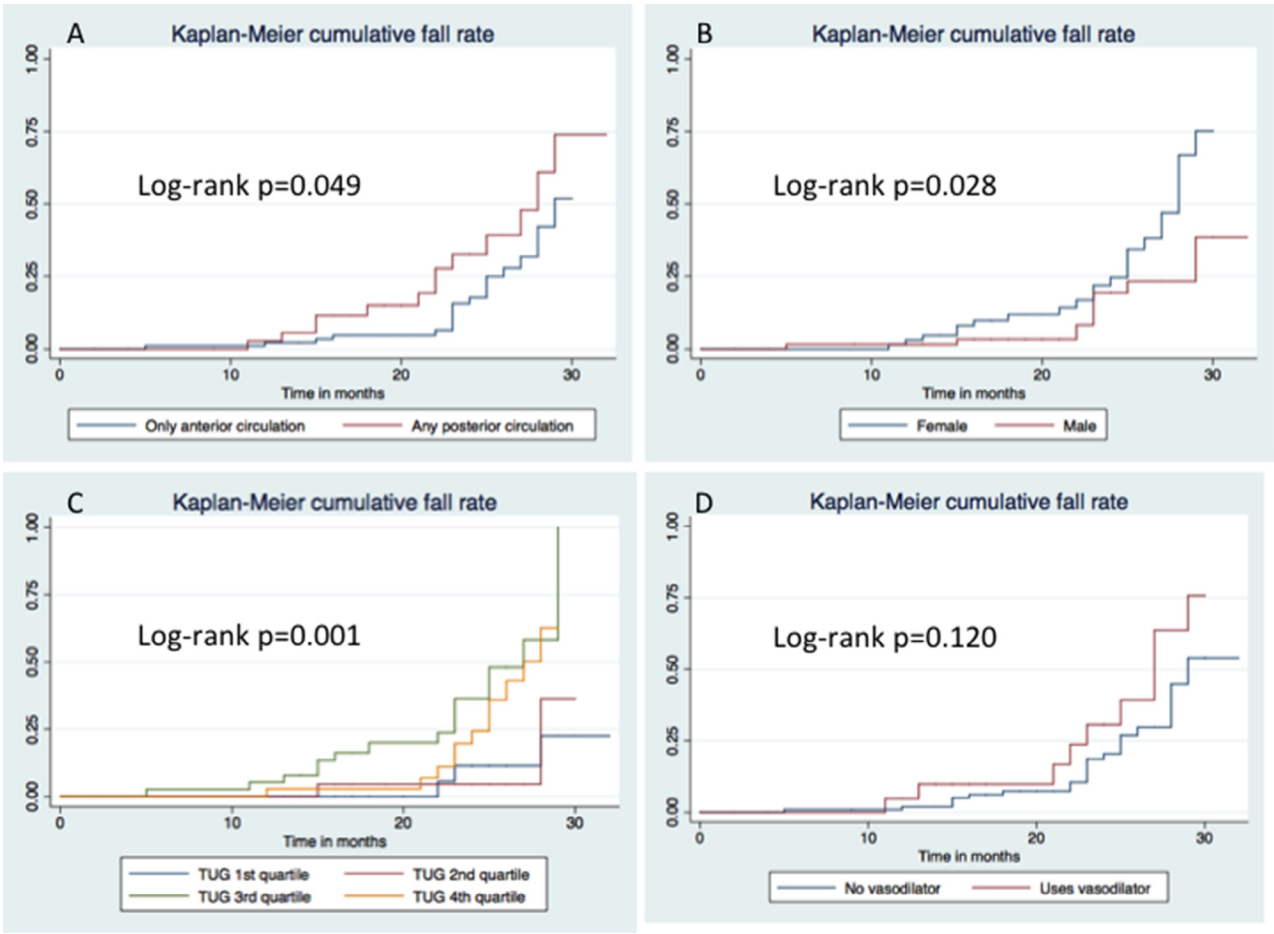

Figure 1. *Distribution of time until occurrence of falls estimated by Kaplan–Meier curves, stratified by demographic and clinical variables in stroke patients living in the community and assisted in an outpatient clinic of an educational institution in the city of Salvador, Bahia. Significant predictors were posterior circulation involvement (A), female gender (B), high TUG time (C), and use of vasodilators (D). Abbreviation: TUG, Timed Up and Go Test.*

Table 2. *Multivariable predictors of recurrent falls in stroke patients living in the community and assisted in an outpatient clinic of an educational institution in the city of Salvador, Bahia*

Variables	Adjusted hazard ratio*	95% Confidence interval	*P* value
TUG quartile	1.69 per 1 quartile increase	1.07-2.69	.026
Posterior circulation involvement	3.37	1.47-7.72	.004
Female gender	2.80	1.08-7.30	.035

Abbreviation: TUG, Timed Up and Go Test.
*Hazard ratio adjusted by previous fall, use of vasodilators, age, and severity of stroke (National Institutes of Health Stroke Scale score).

P = .014) were also significantly associated with increased fall rate.

In Table 3, we used the predictors from the Cox regression model to propose a new recurrent fall risk scale and Figure 2 shows the scale plotted as an ROC curve. C-statistics showed good accuracy (area under the ROC curve = 73%, 95% confidence interval = 62%-83%, *P* = .001). When dichotomized into scores of 2 or lower and higher than 2, the new scale showed 81.3% sensitivity, 41.8% specificity, 31.3% positive predictive value, and 87.2% negative predictive value. The new scale showed an increasing risk of fall associated with increasing scores (Fig 3).

Discussion

The main strengths of our study were the prospective data collection in a reference center and cohort design, which allows a better determination of causality when compared to case–control or case series. In our population, we established that TUG time, female gender, and

Table 3. *New recurrent fall risk scale based on independent predictors from the Cox regression model*

Variable	Values	Points
Timed Up and Go	0-11 seconds	0
	12-14 seconds	1
	15-19 seconds	2
	>= 20 seconds	3
Posterior circulation involvement	No	0
	Yes	2
Female Sex	No	0
	Yes	2

involvement of the posterior circulation were the main predictors of falls in patients living in the community setting.

The TUG is widely used as a valid and secure tool to monitor changes in mobility. The reliability of TUG has been demonstrated both in the elderly and in stroke patients,[18,22] and different studies support its trustworthiness as a predictor of falls.[12,19] Some arguments in favor of the applicability of the TUG have been documented.[10,19,23] One study argues that the TUG contains multiple components of balance and mobility, being related with executive function, in which the transfer and turning

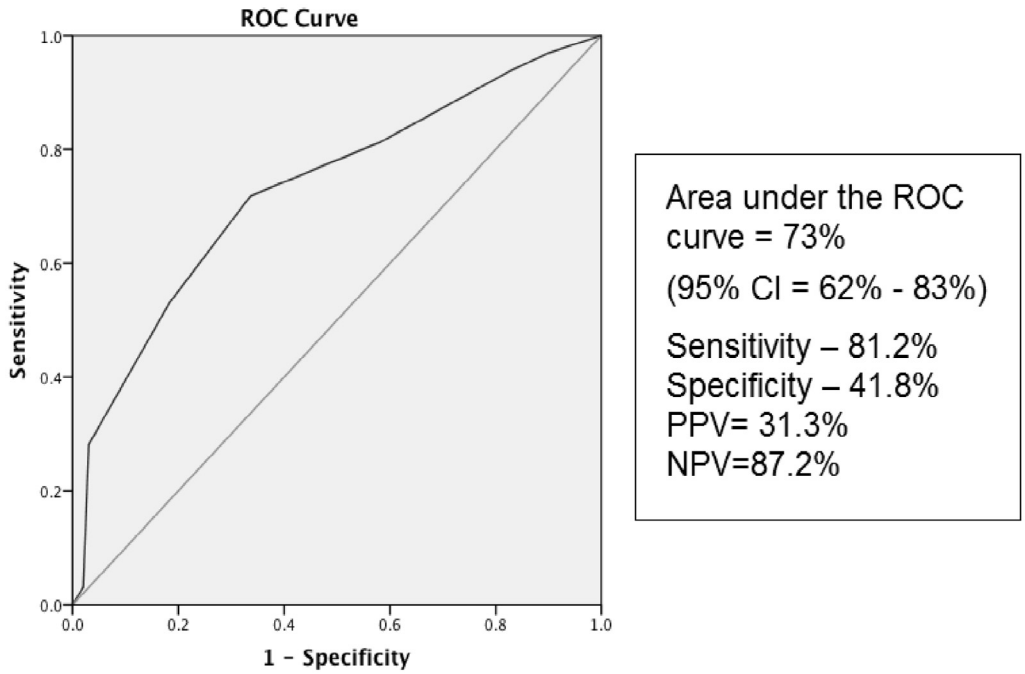

Figure 2. *ROC curve for new fall score. Abbreviations: CI, confidence interval; NPV, negative predictive value; PPV, positive predictive value; ROC, receiver operating characteristic.*

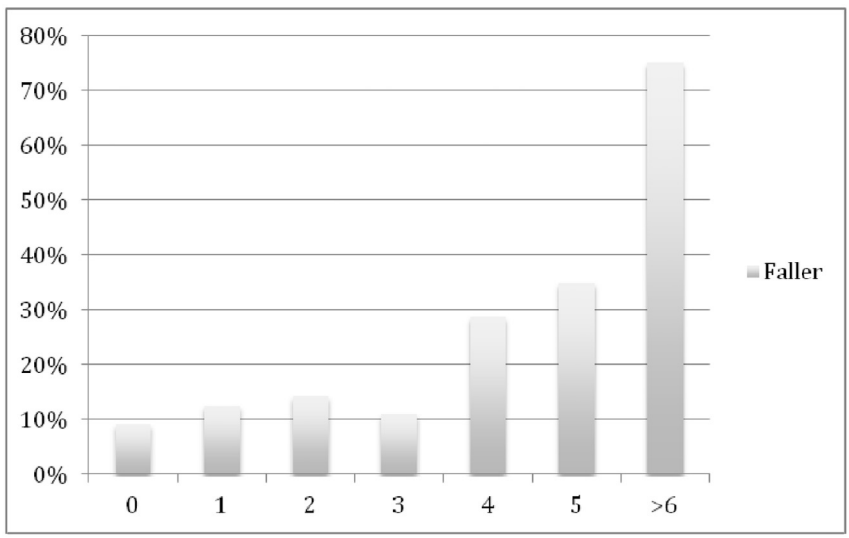

Figure 3. *Risk of recurrent falls for each ordinal score of the new recurrent fall risk scale.*

components help TUG convert a relatively simple motor activity into a more complex measure, which also depends on cognitive resources.[24] Other important aspects that can be raised in favor of TUG are as follows: the TUG tool is objective, fast to apply, requires little equipment, and is easy to perform in a variety of environments.[19,23]

Posterior circulation stroke has several characteristics that can lead to an increased fall rate but may be underestimated by scales evaluating stroke severity such as the NIHSS.[25] Each individual item known to be associated with posterior circulation stroke, such as ataxia and visual field deficit, rarely occurs in isolation.[26,27] One study included the Oxford Community Stroke Project (OCSP) classification as a potential predictor of falls, but no significant association was found.[28] The OSCP is a clinical scale wherein vascular territory is estimated from clinical symptoms and does not use imaging as a criterion to categorize posterior circulation involvement. In our data, we used imaging criteria and found a significant and strong association between posterior circulation involvement and the occurrence of recurrent falls during follow-up.

Female gender has been associated with more frequent falling in the elderly in several studies.[29] In studies with stroke patients, either no difference was found between genders[28,30] or a more frequent falling rate among women was found.[31] The reasons for more frequent falling among women in our cohort are not clear, but may include a combination of lower muscle strength and greater fear of falling when compared to men.[32]

Some researchers have reported an increased risk of falls in the first 6 months after stroke.[9,13,20,33] One study identified a higher incidence of falls in the first 5 months, but falls continued to occur during the 2 or more years of follow-up.[6] The authors acknowledge that factors related to risk of falling may vary over time since stroke, leading to higher or lower incidences, but without eliminating the risk.[6,34] In the present study, with a follow-up of similar duration, the risk of falling remained among individuals, confirming that the time of the stroke is not a significant predictor, as patients fall and continue falling over time. Similar to what was previously reported by other authors, factors such as age,[22,33] previous falling,[35] and the use of mobility aids,[36] often associated with the risk of falls in both the elderly and patients with stroke, were not significant predictors. Another important feature was that, unlike that suggested in a previous study,[37] stroke severity, measured by NIHSS, was not associated with increased risk of falls. In the present study, the sample comprised mostly younger patients who were only moderately affected, and this may have influenced the results.

Similar to what was found in other studies, falls occurred more frequently at home and while individuals walked.[4,34] These findings highlight important aspects to be observed for the implementation of measures related to the individual and their environment that will induce prevention and risk reduction.

The present study shows that development of effective screening tools to determine risk of fall in this population of patients with stroke is an important component of a comprehensive fall reduction plan.[38] It is known that decision making in preventive practices and monitoring of effectiveness of rehabilitation services, in relation to the problem of falls, can be facilitated with the choice of instrument with predictive ability.[39] A range of measures is included in the investigations to identify factors associated with falls in stroke populations[40]; however, the specific factors that would be best associated with an increased risk of falling in this population of patients with stroke remain unclear.[23] Furthermore, falls are influenced by environmental factors, which may differ between individuals in stroke units and in the community.[10,11]

Several groups have attempted to create scales to predict risk of fall, with discrimination varying from poor[41] to moderate.[42,43] Both scales with better discrimination have the same area under the curve as our scale, .73, but use more items to achieve this result (7 items for both scales). Several items from each scale are also subjective impressions from the clinician, such as impulsivity and items from a cognitive evaluation performed in the acute phase of stroke.[42,43] Our scale is simple and includes only 2 items that are easily extracted from stroke admission data and 1 functional mobility item that takes less than 1 minute to evaluate. We also evaluate recurrent risk of fall, which is probably a more significant clinical outcome than a single fall.

Our scale evaluated stroke patients living in the community, so our results may not apply to patients admitted with acute stroke. However, because risk of falling continues after hospital discharge, a scale applicable to community-dwelling patients should be particularly useful for outpatient clinics and rehabilitation centers. We also did not keep a log of patients who were excluded from the study. As in any new scale, our study requires external validation before widespread applicability. Ideally, several of the aforementioned scales should be compared aiming at selecting items with best discrimination.

Conclusions

There was a significant risk of fall in the population evaluated in the present study, regardless of the severity and duration of stroke. The new predictive scale for recurrent risk (including TUG, the compromised posterior circulation, and female gender) is presented as an instrument for monitoring the risk of recurrent falls.

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