Functional Comparison Between Multiple Falls and Non-multiple Falls Groups in Stroke Hemiplegia Patients Six Months After Discharge

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（脳卒中片麻痺患者の退院６ヵ月後における複数転倒群と

非複数転倒群との機能比較）

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Abstract

Objectives: This study focused on examining function 6 months postdischarge to explore any association between specific factors and multiple falls among stroke patients.

Methods: Individuals who experienced two or more falls were classified into the multiple fall group, and individuals with one or no falls were classified into the nonmultiple fall group. These falls were targeted at falls occurring during the first 6 months after discharge from the hospital. Functional assessments for cognition, balance and activities of daily living were performed at 6 months after discharge. Various assessments, primarily the Berg Balance Scale (BBS), were performed to evaluate function related to falls.

Results: Our assessment demonstrated that BBS scores were significantly low among the participants assigned to the multiple fall group. No significant differences were observed in any of the other assessment tools.

Conclusions: Our results indicated that maintaining and improving balance function is an important factor associated with multiple falls in the chronic phase post-stroke. Further validation is needed to apply this conclusion in clinical practice.

Keywords

Balance function, Berg Balance Scale, Chronic stroke, Rehabilitation, Multiple falls

Running title

Falls in Hemiplegic Stroke Patients

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Ⅰ. Introduction

Individuals who have strokes commonly experience falls. Previous studies suggest that approximately 40% of individuals experience at least one fall in the year after a stroke, and approximately 25% of individuals have multiple falls[1,2]. Multiple falls often result in rehospitalization for fall-related trauma such as femoral neck fractures, head injury, or spinal cord injury[1,2], and further increase the economic burden on individuals and decrease the quality of life[2,3]. Multiple falls post-stroke can also lead to depression and an increase in the fear of experiencing recurring falls[4,5]. Several studies have focused on fall prevention, although no rehabilitation program has been shown to effectively reduce the number of falls or the number of fallers following a stroke[4,6]. A better understanding of the factors contributing to recurring falls during the chronic phase of stroke is critical for designing effective rehabilitation programs.

Previous studies have demonstrated that several factors, such as impaired balance, visuospatial neglect, depression, and the number of administered medications, are associated with an increased risk of falls among individuals in the post-stroke phase[7-9]. Most of these studies have often compared individuals who have experienced even a single fall post-stroke with individuals who have not experienced any falls[10]. Balance function appears to be significantly different between individuals who have multiple falls and individuals who do not; however, an interesting finding is that no difference appears to exist between individuals who fall once and individuals who do not fall[11]. In addition, studies examining fall risk post-stroke have primarily focused on assessments performed at the time of discharge. However, the factors that may be associated with falls during the chronic stroke phase are unclear. Hellström et al.[12] showed that individuals with a history of multiple falls had poorer balance and an increased fear of falling. Impaired mobility and balance have been associated with an increased risk of falls 6–12 months post-stroke[13,14]. By contrast, Harris et al.[15] found no correlation between falls and gait or balance function in the chronic stage post-stroke. Furthermore, studies examining factors that could predict the risk of falls during the chronic phase post-stroke have also yielded conflicting results that have been attributed to several flaws, including recall bias (i.e., number of falls), varying study designs, and the categorization of falls[7].

To design effective rehabilitation programs to prevent multiple falls post-stroke, understanding the factors associated with individuals who continue to experience multiple falls during the chronic phase following a stroke is essential. We predicted that the results of an assessment 6 months after discharge would reveal different results from previously reported risk factors for falls. In this study, to better clarify the factors contributing to multiple falls following chronic stroke, we sought to examine functional differences at 6 months post-discharge between individuals who had multiple falls and individuals who did not. We examined the patients at 6 months, because many previous studies have chosen to examine their participants at 6 months. Another reason is that 6 months is sufficient for discharged patients to become accustomed to life in their own homes.

II. Methods

Participants

The participants were selected from stroke patients admitted to an urban rehabilitation facility in the Kansai Region in Japan during two phases: December 2012 to September 2013 and April 2015 to December 2017. Survey validation occurred during the first period, and the second survey was conducted to increase the number of participants tested. Physical therapists recruited stroke patients undergoing rehabilitation at the hospital who fit the inclusion and exclusion criteria. Patients who provided informed and consent for their participation were included in the study. The inclusion criteria were patients diagnosed with stroke hemiplegia and discharged to the community only. The exclusion criteria were patients who had more than one stroke, were not scheduled for discharge from a facility, did not consent to the study, did not understand the study paradigm (to assure cognitive function), lacked mobility within the home, had other diseases or conditions that affected their balance (e.g., artificial joints or spinal diseases), and patients whose physician did not approve of their participation because of any mental illness or patients who were unable to complete the investigation after 6 months. No age limits were required for inclusion in the study. The participants were living independently before the stroke. None of them used devices for mobility. The participants' level of ambulation at discharge was at least independent walking in the home.

Detailed written explanations were provided to the participants or their families, and the study was conducted after the participants provided written informed consent. Sixty-four patients with stroke met the selection criteria and agreed to participate in the study. All patients were provided with the rehabilitation they required at the hospital, which included standing, gait training, daily living training, swallowing training, and speech training. All test participants received rehabilitation within 6 months post-stroke, whereas some participants also received some form of additional rehabilitation at home. The content and duration of the rehabilitation were not uniform because it was tailor-made for each patient. None of the participants changed their place of residence. However, one of the 64 participants in the study could not be contacted and could not be tracked. We obtained approval for this study from the Health Sciences Ethics Committee of the Kobe University Graduate School of Health Sciences (Kobe, Japan; approval number 184) and Kobe Rehabilitation Hospital (Kobe, Japan).

Assessments

All evaluations were conducted by telephone, on record forms, and during hospital visits 6 months after discharge. The evaluation content included age, sex, side of the lesion within the cerebrum, stroke type (i.e., hemorrhage or infarction), number of medications used, and history of falls (at least one fall) during hospitalization, based on the medical record. In most previous studies, the data at the time of discharge from hospital were used, and the number of falls were counted during a 6-month period. In our study, the data at the time of 6 months from discharge was used, and the number of falls were counted during the 6-month period. The fact that data were collected at 6 months is one difference between this study and other studies[10,13,15].

Falls were investigated by a physical therapist via a telephone call to the participants from the 1st month to 5th month post-discharge from the hospital. A fall was defined as an event that resulted in a person coming to rest inadvertently on the ground (or other lower level) that was not a consequence of sustaining a violent blow, loss of consciousness, or the sudden onset of paralysis (e.g., as a result of stroke or epileptic seizure)[16]. Participants or their

families were instructed to fill out a form after each fall. Details of the fall investigation included the presence or absence of a fall, circumstances leading to the fall, and the presence or absence of injury. Every month during the 6-month period, a physical therapist also called to determine whether a fall or suspected event had occurred and asked about the situation. Participants who did not fall or who had a single fall during the 6 months post-discharge were classified into the nonmultiple fall group. Participants who fell two or more times were classified into the multiple fall group. This grouping was chosen because previous reports suggest that fractures are more likely to occur following a second fall, and established guidelines currently do not require a fall risk assessment for a single fall[17,18]. If the participant had a fall without meeting the criteria for a fall, it was classified as an incident.

In-person evaluations were performed 6 months post-discharge from the hospital. Several functional assessments were performed, which have been widely used and do not require special equipment. No falls had occurred in the month before the evaluation, and prior falls had not resulted in injuries that would affect any of the assessment items. Therefore, the impact of falls on each evaluation item was considered small or absent.

Berg Balance Scale (BBS): The Berg Balance Scale (BBS) measures balance ability. It consists of 14 movement tasks used in everyday life, each of which is scored on a scale of 0 to 4. Higher scores indicate better balance ability[19].

Error in estimated reach distance: The error in the estimated reach distance was defined as the difference between the predicted and the actual reach distance in centimeters[20]. This method was used to evaluate each participant's understanding of their physical functions. The method measured the error between the distance predicted that an individual would be able to reach in the standing position and the distance actually reached.

Comfortable gait speed (10-m gait): Comfortable gait speed was used to assess gait function and measure the time in seconds taken by the participants to walk 10 m. Gait speed was measured in m/s[21]. Participants who could not walk without a cane or other device were allowed to use the device.

Dual task: This task involved a test of walking 10 m while serially subtracting 7 from 100 to assess attention function during walking. The test measured the time in seconds that the participants needed to walk 10 m.

Functional independence measure (FIM): The FIM measures the independence of an individual in performing daily life tasks. It consists of 18 items that measure motor function (FIM-M; 13 items) and cognitive function (FIM-C; 5 items). The items are scored 1–7 points. Higher scores indicate greater independence[22]. The FIM was scored by the researcher via interviewing the examinees.

The Mini-Mental State Examination: This 30-point questionnaire is used to assess cognitive function[23].

Trail Making Test A (TMT-A): The TMT-A is a test for attentional disorders[24]. It is a pencil and paper test that is scored, based on the seconds required to complete the test.

Statistical analysis

Comparisons between the two groups were conducted, based on assessments performed 6 months post-discharge. Group differences were assessed using the chi-square test, the Mann–Whitney *U*-test and unpaired *t*-test. The Mann–Whitney *U* test was used for interval scales that did not show a normal distribution. SPSS software ver.

29 (IBM Corp., Armonk, NY, USA) was used for all statistical analyses. The significance level was set at 5%. Data at discharge were not used in this study because the focus was on using data after 6 months.

III. Results

The participants' characteristics and evaluation scale values are listed in the Table 1. The participants comprised 35 men and 29 women with a mean age of 66.09 ± 12.71 years. Among the 64 participants, 16 participants had multiple falls (i.e., multiple fall group), and 48 participants experienced no or only one fall (i.e., nonmultiple fall group). The timing of fall occurrence for the multiple fall group is presented by month in Table 2 . Pearson's chi-square test and adjusted residue analysis revealed that falls in the multiple fall group occurred more often within 2 months of discharge. A history of falls during hospitalization affected 16 (50%) participants in the nonmultiple fall group and 6 (60%) participants in the multiple fall group. Among the 64 participants, 16 (25%) participants had multiple falls after discharge and 48 (75%) participants had one or no falls. Among the nonmultiple fall group, 14 participants experienced only one fall. Some participants with multiple falls had fallen four times. The participants who experienced falls had only cuts and bruises but no injuries that affected their daily lives or the assessment items.

At 6 months post-discharge, the BBS was significantly lower in the multiple fall group, suggesting that the balance function of the nonmultiple fall group was significantly better than that of the multiple fall group. No significant differences were observed in the other assessed functions (Table1).

Table 1: Comparison of the Multiple and Nonmultiple Fall Groups at 6 Months Post-discharge

Evaluation tool	**Nonmultiple fall group (n=48; 75%)**	**Multiple fall group (n=16; 25%)**	**P-value**	**95% Confidence interval**		**Effect size**
				Lower confidence limit	**Upper confidence limit**	
Sex (male/female)	29/19	10/6	0.111[a]	-	-	
Disease type (hemorrhage/infarction)	17/31	4/12	0.414[a]	-	-	
Lesion side (left/right)	33/15	9/7	0.362[a]	-	-	
Incidents (present/absent)	19/29	6/10	0.882[a]	-	-	
History of falls in the hospital at discharge (present/absent)	16/32	6/10	0.761[a]	-	-	
Age (y) [b]	65.5±12.9	67.9±12.5	0.525[c]	-10.00	5.00	0.080
BBS [b]	51.2±4.9	48.6±4.5	0.044[c]	0.00	6.00	0.252
MMSE [b]	27.8±2.1	27.7±4.1	0.430[c]	-1.00	1.00	0.099
TMT-A (seconds) [b]	156.4±51.0	370.3±581.2	0.306[c]	-46.71	21.04	0.128
FIM [b]	120.0±5.5	117.0±7.3	0.152[c]	-1.00	6.00	0.179
FIM-M [b]	85.9±5.3	83.5±6.0	0.146[c]	-1.00	5.00	0.182

FIM-C [b]	34.3±1.3	33.5±3.2	0.262[c]	0.00	1.00	0.140
10-m Gait (seconds) [b]	14.3±7.7	19.1±11.4	0.114[c]	-7.22	0.87	0.198
Dual task (seconds) [b]	17.9±10.2	25.0±18.8	0.060[d]	-14.51	0.30	0.200
Error in estimated reach distance (cm) [b]	7.5±6.7	10.5±7.7	0.187[c]	-7.30	1.10	0.165
Number of medications used [b]	5.1±3.1	5.9±3.1	0.289[c]	-2.00	1.00	0.133

[a] Based on the chi-square test.
[b] The data are presented as the mean±SD.
[c] Based on the Mann–Whitney *U*-test.
[d] Based on the unpaired *t*-test.

BBS, Berg Balance Scale; MMSE, Mini-Mental State Examination; TMT-A, Trail Making Test A; FIM, Functional independence measure FIM-M, Functional independence measure–motor function; FIM-C, Functional independence measure–cognitive function; SD, standard deviation

Table 2: Number of Falls per Month up to 6 Months After Discharge in the Multiple Fall Group

After discharge	1 month	2 months	3 months	4 months	5 months	6 months
Total number of falls	11	12	9	3	5	3
Pearson's chi-square test			$P < 0.01$			
Adjusted residual	2.3	2.9	1.0	-2.9	-0.3	-2.9

IV. Discussion

In this study, we explored factors associated with multiple falls in stroke patients 6 months post-discharge from the hospital. Most studies have focused on potential factors that may predict the risk of falls post-stroke and have assessed physical and mental function at the time of discharge from the hospital[25,26]. We examined patients 6 months after discharge from the hospital to better understand the factors associated with multiple falls in chronic stroke. Our data showed that individuals in the nonmultiple fall group had significantly better balance functions than did individuals in the multiple fall group.

Most falls in the post-discharge multiple fall group occurred within 2 months of discharge from the hospital. This finding may be because of the change in the environment after discharge from the hospital. Even in a familiar housing setting, adapting to the new environment was difficult for patients because of the changes in their physical condition caused by the stroke.

Previous reports have shown that women have more falls[27]. No significant difference existed between men and women in the current study. However, our study had more men than women. Falls have also been reported as significantly more common in individuals with right hemisphere injuries[28]. In addition, compared with left-hemisphere damage, right hemisphere damage is more likely to produce unilateral spatial neglect[29], and visuospatial

hemi-neglect increases the risk of falls post-stroke[8]. We found a higher percentage of right-sided injuries in the multiple fall group; however, no significant difference existed in the lesion side between the two groups.

A history of falls has been associated with recurrent falls[30]. A higher percentage of individuals in the multiple fall group had a history of falls during hospitalization. However, we found no significant difference between the two groups in this study, which may have been influenced by differences in the sample sizes between the two groups.

Previous reports have demonstrated that the FIM is lower in the fall group[31,32]. In this study, the overall FIM, FIM-M, and FIM-C scores were investigated, but no significant differences existed. A possible explanation is that, because the criteria for inclusion in this study involved understanding the research content and the ability to ambulate, the FIM was high in all individuals.

Most falls reportedly occur while walking[33]. Individuals in the multiple fall group tended to take longer to walk 10 m, although no significant difference existed in the 10-m gait. Daily life activities do not always involve walking in a straight line or focusing on the sole task of walking alone. To assess attentional function during walking, a dual task was conducted. The dual task took longer in the multiple fall group, but the difference was not statistically significant. Although previous studies have indicated that performance on a dual task is associated with falls[34], we did not find any significant effect in our study. However, the dual task took longer in the multiple fall group.

Previous studies[20] have shown an association between the error in the estimated reach distance and falls. A possible explanation is that strokes affect body image perception, which could affect falls post-stroke. No significant difference existed in the error in the estimated reach distance between the multiple and nonmultiple fall groups in our study, suggesting that rehabilitation may have altered body image and thus resulted in no significant difference.

The number of medications taken has been associated with falls in previous studies, with a previous study showing that the risk of falls is increased in individuals taking more than 8.5 medications[7]. In the present study, we found no association between the number of medications taken and falls. However, both groups were prescribed fewer than 8.5 medications, which may have contributed to the lack of an effect. The drugs were not taken PRN.

Most of the other factors examined at 6 months post-discharge from the hospital did not show any significant associations between multiple fallers and non-fallers; however, we found a significant effect on balance function between the two groups. A recent study by Kossi et al.[35] found that post-stroke duration was significantly associated with balance impairments, and the recovery of balance function was associated with rehabilitation. This finding suggested that, in contrast to other factors, the prevention of multiple falls may require that the balance function is maintained at a high level, even after 6 months. The BBS score reportedly has high reliability in predicting falls post-stroke[36] and is significantly lower in individuals with recurrent falls[37]. We observed falls over a 6-month period and were unable to analyze them on a monthly basis. This factor means that determining how frequent falls occurred in the post-discharge period was not possible.

This study differs from previous studies in that our evaluations were consistently conducted after 6 months. The participants underwent rehabilitation every day during their hospitalization. Once the participants are discharged, rehabilitation typically ceased or decreased in frequency, thereby resulting in possible functional changes.

We aimed to identify the factors associated with multiple falls in the chronic stroke phase at 6 months post-discharge. We predicted that the results of the assessment 6 months after discharge would reveal different results from previously reported risk factors for falls. However, balance, which has been associated with multiple falls in the past, was also had an effect on multiple falls in this study. The results suggested that stroke patients who have multiple falls can be prevented from falling with good balance, even if they have problems with cognitive and attention functions. The results of this study suggested that maintaining balance function is important for minimizing falls after discharge. Thus, implementing interventions that help maintain balance, even after discharge, is important.

The limitations of this study are that it was restricted to a single institution with a small number of participants, which may have contributed to the lack of significant effects on several of the physical functions examined. Furthermore, the small sample size did not allow for satisfactory statistical analysis. A sufficient sample size would have allowed for multivariate and factor analysis. In addition, only a few factors were examined, and this study did not examine the relationship between the factors. Another possible limitation is that the housing environment was not consistent. Although housing conditions may affect falls, we do not believe a significant difference existed between housing conditions for the condominium and detached house types because condominiums have elevators. Moreover, postdischarge conditions were not constant because patients were not discharged from the hospital with or without rehabilitation, and the frequency of rehabilitation and self-training were not constant. Considering the fact that the results of this study have not proven to be sufficiently different, we believe that several processes are needed before the results of this study can be applied in clinical practice. These processes are to determine how a patient's balance is maintained over time after discharge from the hospital and to determine whether balance is affected by falls that occur soon after discharge and falls that occur long after discharge. Future studies should be conducted in multiple facilities and larger sample sizes should be utilized to mitigate these limitations.

V. Conclusion

Various factors have been reported to contribute to falls in stroke patients. This study found a significant difference in the BBS at 6 months after discharge between the multiple fall group and the nonmultiple fall group of stroke patients, which indicated that balance affects multiple falls. Further investigation of multiple falls and post-discharge function in stroke patients should be conducted in the future.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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