ORIGINAL

Long-term outcome of severe stroke patients : Is the ADL status at discharge from a stroke center indicative of the long-term outcome?

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Abstract : The objective of this study was to examine the possibility of predicting the long-term outcome of severe stroke patients from the ADL status at discharge. The design is a retrospective observational study in the stroke center at Tokushima University Hospital. Severe stroke patients at discharge with Barthel Index (BI) scores $\leq$ 40 (N=51) were divided into two subgroups retrospectively, improved and unimproved. The Functional Independence Measure (FIM) and BI were analyzed at discharge, 3 and 6 months after onset. Correlation analysis between BI and FIM showed good correlation, especially between BI and motor FIM (mFIM). In conclusion, the ADL status at discharge from a stroke center is not definitely indicative of the long-term outcome, although good recovery of severe stroke cases was observed in males and younger patients, and in patients with motor FIM score >25. This result shows that the first 3 months after the attack should be regarded as an important time window for intensive rehabilitation. J. Med. Invest. 58 : 227-234, August, 2011

Keywords **:** *stroke, outcome, barthel index, functional independence measure, long term*

INTRODUCTION

Recently in Japan, most stroke patients have been transferred to a rehabilitation hospital just after critical acute treatment. The objective of the study was to clarify whether future recovery from a severe condition at discharge is predictable. Nakao *et al.* (1) used Barthel Index (BI) (2) as an outcome of stroke, which is far simpler than Functional Independence Measure (FIM) (3), and concluded that a BI score > 40 at discharge can predict eventual good activities of daily living (ADL). In this study, we used the same database to examine severe stroke patients, BI score $\leq$ 40, to explore the possibility of predicting the long-term outcome. This database includes a large number of indicators. For precise examination of the condition, we used motor and cognitive FIM scores combined with BI. The correlation between BI and FIM will also be discussed in detail.

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METHODS

(1) Setting and participants

In this study, a series of 542 consecutive acute stroke inpatients admitted to our hospital in 2007-2008 was used, and a complete database was gathered for 221 cases (135 infarction, 54 hemorrhage, 29 subarachnoid hemorrhage), from which 51 severe patients (19 infarction, 27 hemorrhage, 5 subarachnoid hemorrhage) with a BI score ≤ 40 were selected. Our stroke treatment is based on the Japan Guidelines for the Management of Stroke (4), which is regarded as state of the art. Intravenous tissue plasminogen activator (tPA) can be administered to an ischemic stroke patient within 3 hours after onset. Rehabilitation is initiated within a few days after admission. A seamless relationship between acute and chronic hospitals or clinics was established in 2007 in the Tokushima region. Outcome data were collated and sent on CD-ROM by these treatment facilities. The data were processed according to the ethics rules for the management of personal information.

(2) Outcome measures

The objective of this study is to study severe and complicated cases with a BI score 0-40 at discharge from the Stroke Center. In this setting, we analyzed mFIM and cognitive FIM (cFIM) in addition to BI and total FIM (tFIM or FIM) change over time.

(3) Methods of analysis

The time course, from discharge to 6 months, of the BI score in severe stroke was compared with the mean value. Severe stroke patients were divided into two subgroups : an improved group, which achieved a score >40 at 6 months after onset, and an unimproved group. These two groups were compared from the viewpoint of mFIM and cFIM. The contribution of age or gender was additionally analyzed. The correlation between BI and FIM was analyzed using Pearson's correlation coefficient test for total and severe cases separately. Chi-square test was performed to verify independence. All analyses were carried out using Microsoft Excel software (Microsoft Corp., Redmond, WA, USA) add-on software Statcel2 (Oms-publ., Tokorozawa, Japan).

RESULTS

(1) Correlation analyses between BI and FIM, in total cases and severe cases

We examined Pearson's correlation between BI and mFIM, between BI and tFIM, and between BI and cFIM at discharge in all cases (N=542). Figure 1

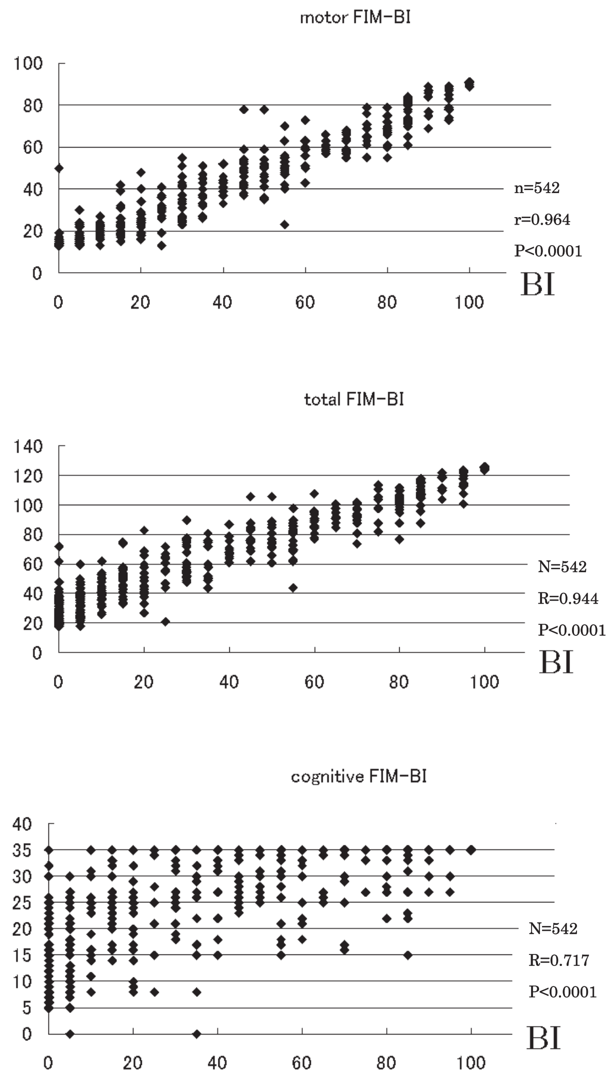

Figure 1. FIM-BI correlation in total cases.
(upper : motor FIM-BI, middle : total FIM-BI, lower : cognitive FIM-BI)
A good correlation between BI and motor FIM ($r=0.964$, upper) ; BI and total FIM also correlated with a coefficient r of 0.944 (middle) ; however, BI and cognitive FIM showed a weak correlation ($r=0.717$, lower).

(upper) shows a good correlation between BI and mFIM (coefficient (r)$=0.964$) and BI and tFIM with a coefficient of 0.944 (Figure 1 (middle)) ; however, BI and cFIM showed a weaker correlation ($r=0.717$, Figure 1 (lower)). There was a linear relationship between mFIM and BI, and between tFIM and BI. The following formulas were obtained from single regression analysis :

$mFIM=0.734 \cdot BI+13.1$ (P for BI=0 ; P for constant=1.5E-187),

$tFIM=0.968 \cdot BI+27.9$ (P for BI=6E-287 ; P for constant=8.3E-187),

where E is the exponent and P is the P-value of a t-test.

We also examined Pearson's correlation in patients with BI ≤ 40 (N = 51). BI and mFIM correlated highly with coefficients of 0.953 on admission, 0.946 at discharge, and 0.974 at 3 months (Table 1). In contrast, mFIM and cFIM correlated with smaller r values of 0.335 on admission, 0.535 at discharge, and 0.721 at 3 months. The severe case group also showed a good correlation between BI and motor FIM, but a weaker correlation between mFIM and cognitive FIM at discharge. The t-test is used to establish the statistical significance of the correlation coefficient. Table 1 shows that the coefficient is highly significant, except between mFIM and cFIM. The correlation between BI (or mFIM) and cognitive FIM was weakened by the group of cases with high cognitive scores and low BI scores in the analysis of total cases, and the correlation was weakened by the group of cases with low cFIM and high BI (or mFIM) scores in severe cases.

(2) Classification of severe cases

Fifty-one severe cases were divided into two groups : patients who showed improvement after discharge and achieved a BI score of more than 40 (improved group, 28 cases), and those who did not exceed the BI score of 40 until 6 months after onset (unimproved group, 23 cases). The improved group showed gradual recovery of the BI score, and the mean value reached to 60 at 6 months, whereas the unimproved group showed a slight fall at 6 months. These time courses are shown in Figure 2.

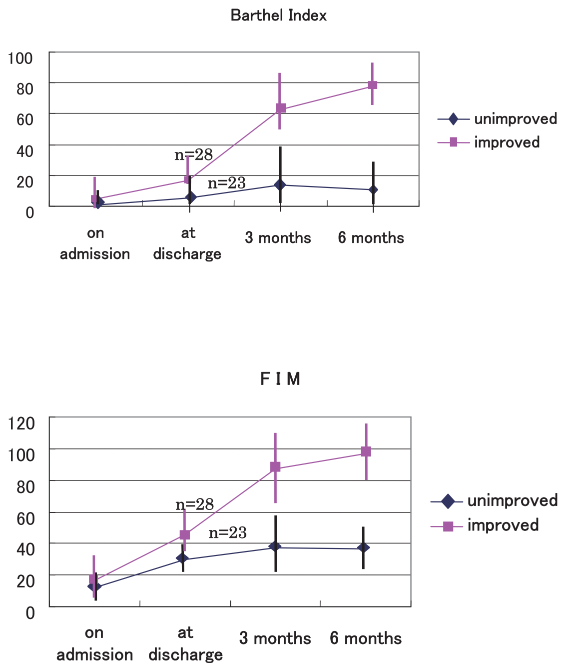

Figure 2. Time course of severe cases in 2 subgroups.
(upper : BI, lower : FIM, improved : improved group, unimproved : unimproved group)
The improved group showed gradual recovery of the BI and FIM scores, whereas the unimproved group showed a slight fall at 6 months.

Table 1. Correlation between ADL measures examined in the time course.
(BI : Barthel Index, FIM : Functional Independence Measure, mFIM : motor FIM, tFIM : total FIM, cFIM : cognitive FIM, unimproved : unimproved subgroup, improved : improved subgroup)
BI and mFIM exhibit a very close correlation. A smaller correlation is noted between mFIM and cFIM ; the coefficient is especially low in the improved group at 3 months in this table.

day of exam (subgroup)	Correlation between	cases	Coefficient (r)	t-value	P-value	t (0.975)
on admission	BI, mFIM	50	.953	21.8	< 0.0001	2.00
	BI, tFIM	50	.791	8.96	< 0.0001	2.01
	mFIM, cFIM	50	.335	2.46	0.0171	2.01
at discharge	BI, mFIM	51	.945	20.42	< 0.0001	2.00
	BI, tFIM	51	.886	13.40	< 0.0001	2.00
	mFIM, cFIM	51	.535	4.43	< 0.0001	2.00
at 3 months	BI, mFIM	45	.974	28.41	< 0.0001	2.01
	BI, tFIM	45	.959	22.35	< 0.0001	2.01
	mFIM, cFIM	45	.720	6.81	< 0.0001	2.01
at 3 months (unimproved)	BI, mFIM	19	.968	16.13	< 0.0001	2.10
	BI, tFIM	19	.929	10.42	< 0.0001	2.10
	mFIM, cFIM	19	.724	4.33	0.0004	2.10
at 3 months (improved)	BI, mFIM	26	.914	11.05	< 0.0001	2.06
	BI, tFIM	26	.878	8.99	< 0.0001	2.06
	mFIM, cFIM	26	.388	2.06	0.0500	2.06

(3) Motor FIM and cognitive FIM as indicators of recovery

Motor function and cognitive function at discharge were compared in these two groups, improved and unimproved (Figure 3). In severe stroke cases, cFIM exhibited small scores ≤ 25 in almost all cases. The patients with mFIM > 25 subsequently showed an improving tendency. On the other hand, low scores of mFIM did not always preclude the possibility of recovery in the future. Nearly half of the patients with motor FIM < 25 showed improvement until 3 to 6 months.

(4) Difference of mFIM-cFIM correlation between improved and unimproved groups

The correlations between mFIM and cFIM at discharge are shown in the lower part of Table 1. In regard to the mFIM-cFIM correlation, the coefficient was 0.724 in the unimproved group, which was higher than that of the improved group (0.388).

(5) Characteristics of severe cases

(a) Disease distribution

Figure 4 shows the difference in stroke types in severe cases in reference to total cases. In total cases, in the upper panel of the figure, cerebral infarction occupies 60% of the cases and cerebral hemorrhage is 24% ; however, cerebral hemorrhage comprises 53% of severe cases, in the lower panel of the figure. The ratio of infarction/hemorrhage was nearly reversed in severe cases.

(b) Age in the severe group

The average age was 69.8 ± 23.3 (SD) in total cases in the stroke center. In severe cases, the average age was 70.5 ± 10.1 (SD). There was no difference in age between total cases and severe cases.

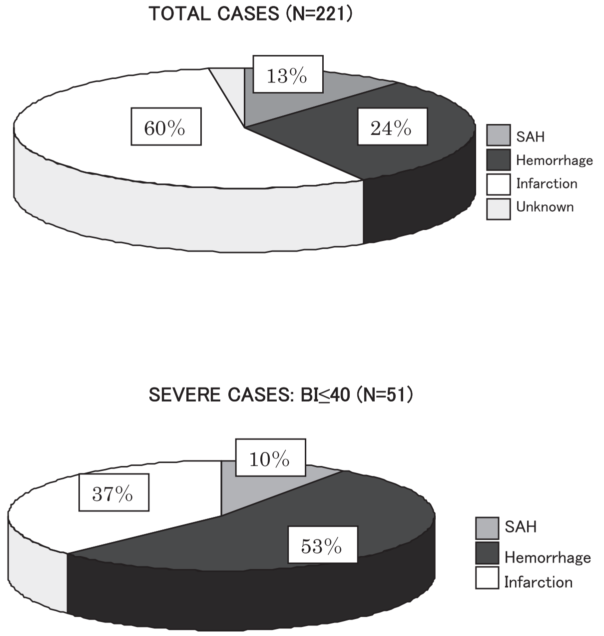

Figure 4. Distribution of the disease.
upper : total cases, lower : severe cases
Cerebral infarction occupies 60% in total cases, whereas cerebral hemorrhage increases to 53% in severe cases.

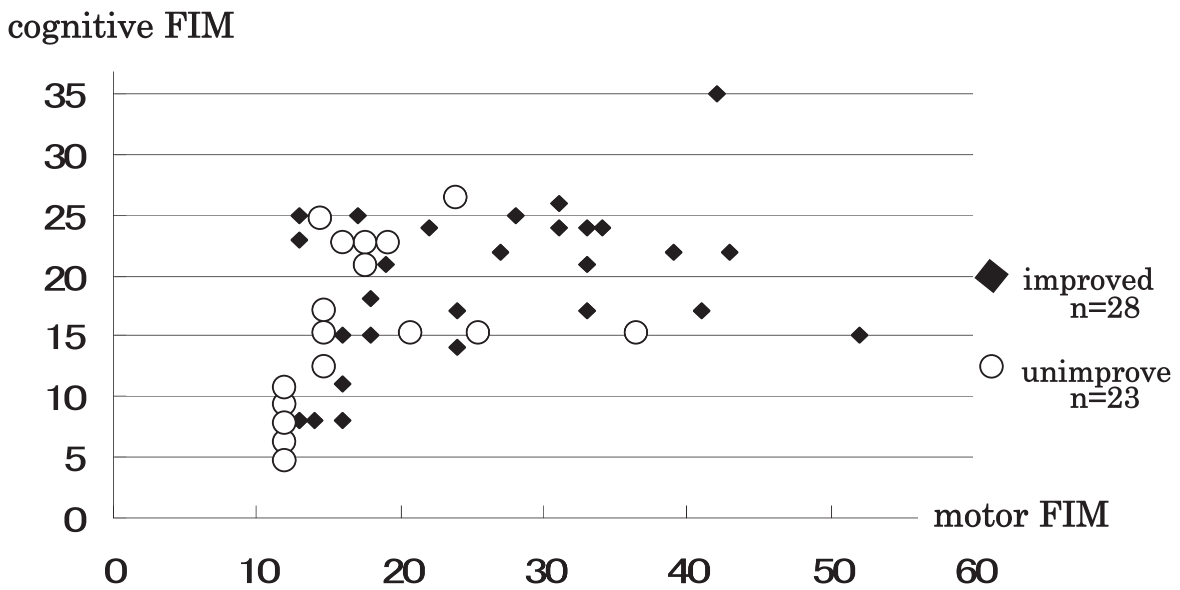

Figure 3. Scatter plot of cognitive FIM-motor FIM in severe stroke cases.
Low scores of motor FIM ≤ 25 did not preclude the possibility of recovery in the future. Nearly half of the cases showed improvement.

(6) Comparison between improved group and unimproved group

The improved group was younger (N=28, mean : 66.5±8.7) than the unimproved group (N=23, mean : 76.1±8.7, P<0.01).

Figure 5 shows the role of gender in relation to the improvement after severe stroke. There were 23 male patients and 27 female patients. Eighteen male and 10 female patients improved, but 6 male and 17 female patients did not improve. Statistical examination revealed a difference in recovery with regard to gender (χ^2-test, P<0.01).

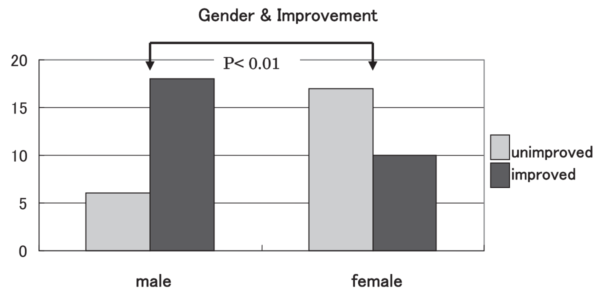

Figure 5. Gender in relation to the improvement after severe stroke.
Males show an improving tendency compared with females.

DISCUSSION

The BI was devised by Barthel *et al.* in 1965 (2) and is used mainly in European countries as a simple and useful evaluation of a patient's independence. It can be accurately and quickly scored by adhering to the definition of 10 items concerning ADL, and the score range is 0-100. FIM was developed by Granger *et al.* in 1983 for precise evaluation of ADL (3), and is the main tool in the USA (5). FIM is divided into two sections : a motor section, which includes 13 items, and a cognitive section, including 5 items. Each item is graded from 1 (totally dependent) to 7 (completely independent), and the tFIM score range is 18-126 (mFIM : 13-91, cFIM : 5-35). Many studies have compared the BI and FIM (6-10). Although recent studies from North America were more likely to use the FIM (11), the BI is a simple method that has been used more often than FIM. Our study showed a close correlation between BI and FIM scores ; in particular, BI scores and mFIM scores were very closely correlated (Table 1). From this standpoint, BI holds a dominant place because of its simplicity, whereas the FIM is useful to assess cognitive function separately.

The Deming cycle, plan-do-study-action, is a well-known system for total quality control. In the rehabilitation process of stroke, it is also important to plan suitable action according to the patient's ADL. A large proportion of the literature is concerned with the prediction of post-stroke disability (1, 11-17). Recent specific therapy and interventions are said to be associated with better outcomes. Our Stroke Center was established in 2005 with state-of-the-art treatment, including rehabilitation. It may be reasonable to discuss the possibility of prediction in these settings. We analyzed the database of Stroke Center inpatients during 2007-2008, with follow-up until 6 months after onset. Nakao *et al.* (1), who used the same database, found that a BI score >40 at discharge is an excellent indicator of better prognosis in the chronic stage (Figure 6). Then, we focused on severe stroke patients with a BI score ≤40. These patients were a mixture of with and without good recovery. The main objective of the study was to clarify whether further classification of severe cases in regard to the outcome is possible.

The correlation between BI and cFIM was weakened by two groups of cases, one with high cognitive scores and low BI scores, and the other with low cFIM and high BI scores. We consider that these two groups seem to correspond to lacunar infarction and dementia, respectively, because cognitive function is preserved in most lacunar infarctions

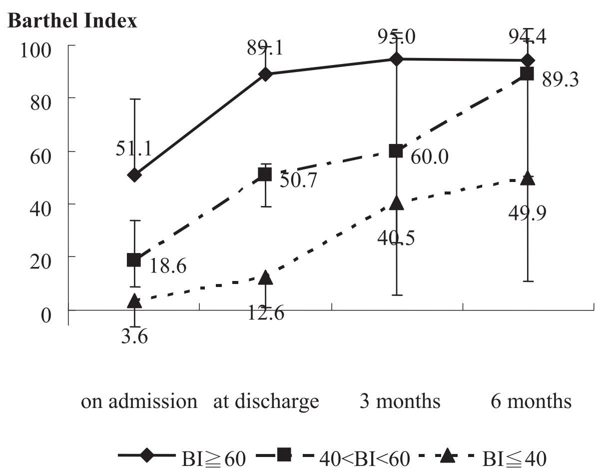

Figure 6. Changes of Barthel Index (BI) in each score range (Nakao *et al.* 2010, with permission from The Journal of Medical Investigation)
Although all ranges improved, patients with a BI > 40 on discharge improved more than patients with a BI < 40. Patients with a BI > 60 on discharge maintained the same level at 6 months.

(18) and individuals with dementia sometimes suffer strokes ; therefore, lacunar infarction and dementia should be taken into consideration in BI-cFIM interaction.

In severe cases, cFIM scores were mostly ≤ 25, both in the improved group and in the unimproved group. Higher mFIM scores, > 25, showed a recovery tendency ; however, low mFIM scores, < 25, did not always indicate no change. Almost half of the patients with mFIM scores < 25 belonged to the improved group (Figure 3). In mild stroke, good cognitive function seems to facilitate better recovery (1) ; however, our study of severe stroke showed that cFIM did not correlate with better prognosis. In severe stroke, cognitive failure is a common feature and the recovery seems to be slow or difficult (19, 20). Speech therapy and rehabilitation for higher brain dysfunction, which are now used in our facilities, have a limit to achieve useful recovery of ADL. More specialized long-term rehabilitation should be applied to regain cognitive function.

It is fundamentally important to reduce cases of severe motor deficit in acute-stage treatment, or more fundamentally to prevent stroke. Until such an innovation, the most important procedure is aggressive rehabilitation for at least 3 months, and if possible, more than 6 months after the onset of stroke (21). The capability of severe stroke patients is not completely predicted from the ADL at the stage of discharge from a stroke center. Treatment at a stroke center produces immediate recovery in some cases, but in others the symptoms subside gradually after discharge. Good recovery is initiated as a result of early rehabilitation in the acute stage, and strengthened by following rehabilitation for 3 to 6 months. We regard the first 3 months after onset as an important period for intensive rehabilitation, and the rehabilitation team should work hard during this period, regardless of the ADL level at discharge, until a more effective method is developed in the future (19, 22, 23).

Statistical examination showed that male and younger patients have a greater possibility of recovery. The reason why gender and age play roles in the process of recovery from severe stroke is unknown, but muscular power and balance activity seem to play important roles in the rehabilitation and recovery process. Roth *et al.* evaluated gender differences in 1-year outcomes for stroke survivors and concluded women are at heightened risk for poor outcomes (24). Kay *et al.* investigated nontraumatic spinal cord injury and found men were more independent in mobility than women in the most disabled group (25).

LIMITATIONS

The number of severe cases is insufficient for study subgroups, for example, the type of disease, location of the lesion, and age groups. This suggests that larger studies with tighter controls on the case mix may provide additional information on stroke patients. This study will assist in the interpretation of BI and FIM scores and the direction of stroke therapy in the near future.

This study is a statistical study to predict outcome. Case studies are valuable to estimate the individual outcome utilizing MRI tractography, evoked potentials, and actigraphy, which show the possibility of recovery after the reduction of brain edema after the attack (15-16, 26-29).

CONCLUSIONS

In severe stroke patients, no accurately predictive ADL factor for good recovery was found at discharge from the stroke center. Although patients with mFIM scores > 25, male and young showed a recovery tendency, low mFIM scores < 25 do not always preclude improvement. Almost half of the patients with mFIM scores ≤ 25 belonged to the improved group. There is hope for good recovery in a severe stroke patient during the first 3 to 6 months after the attack. We should continue to do our best for patient rehabilitation during this period.

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