

Original Article



Factors Associated with Changes in Functional Independence after Six Months of Ischemic Stroke

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HIGHLIGHTS

- This study demonstrated the changes in functional independence and their associated factors during the first 6 months to 1 year after stroke onset.
- Obesity showed a positive influence on the Korean version of Modified Barthel Index score, while depression showed a negative influence.

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ABSTRACT

The aim of this study is to investigate the changes in functional independence and their associated factors during the first 6 months to 1 year after stroke onset. This study is the interim results of the Korean Stroke Cohort for Functioning and Rehabilitation. A total of 1,011 participants were included and classified into 3 subgroups according to changes in the Korean version of Modified Barthel Index (K-MBI) scores that occurred between 6 months to 1 year after stroke onset: the improved group (IG), with scores that increased 5 points or more; the stationary group (SG), with the K-MBI score changes ranging from -4 to +4 points; and the declined group (DG), with the K-MBI scores that decreased 5 points or more. Ordinal logistic regression analyses were used to assess the factors influencing changes in the K-MBI score. Among 1,011 patient, 436 patients (43.1%), 398 patients (39.4%) and 117 patients (17.5%) were classified into the IG, SG, and DG, respectively. Obesity and Geriatric Depression Scale score were significant influencing factors for changes in the K-MBI scores. Obesity showed a positive influence on the K-MBI score, while depression showed a negative influence.

Keywords: Activities of daily living; Stroke; Obesity; Depression

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Conflict of Interest

The authors have no potential conflicts of interest to disclose.

INTRODUCTION

Stroke is a major cause of serious long-term disability and causes a great burden on patients, caregivers, and the community [1]. Although age-standardized rates of stroke mortality have decreased in the past 2 decades, the absolute number of people who have a stroke annually and the number of stroke survivors are increasing [2,3]. Therefore, an increase in the incidence of nonfatal strokes may result in an increase of the number of stroke survivors with disability, hence generate an economic burden of society [4,5].

Maintaining functional independence in activities of daily living (ADL) is an important factor for preserving the quality of life (QOL) of stroke survivors [5,6]. Therefore, reducing disability and improving functional independence of stroke survivors is the primary goal of poststroke management [7]. Almost all stroke patients recover to a considerable extent, yet only 64.1% of patients achieved functional independence 6 months after stroke onset [8]. Knowledge related to the recovery period and long-term outcomes after stroke is important in determining the appropriate treatment and timing of rehabilitation. Longitudinal studies show that most functional recovery occurs within the first few months after a stroke, and the recovery slope reaches a plateau between 3 and 6 months [9-12]. However, the clinical manifestations of stroke patients are heterogeneous, and each individual recovery pattern is different. Formal studies have focused on the average recovery pattern that occurs in the general stroke population, which is not necessarily a good indicator of individual recovery [9,10,12].

We hypothesized that, although meaningful recovery usually ends after 6 months in a large-scale population, functional recovery can be variable at the individual level. Identifying the factors related to the improvement of function after 6 months may prove helpful for planning poststroke management in stroke patients. In this study, we analyzed changes in functional independence 6 months after stroke onset and investigated the factors associated with improvement of functional independence from 6 months to 1 year after onset in first-ever ischemic stroke patients.

MATERIALS AND METHODS

Study population and baseline characteristics

This study is an interim report of the Korean Stroke Cohort for Functioning and Rehabilitation (KOSCO), a cohort of first-ever acute stroke patients who were admitted to participating hospitals in 9 different areas of Korea. The KOSCO study was designed as a 10-year, long-term follow-up study of stroke patients. It is a prospective, multi-center project investigating the factors that influence residual disabilities, activity limitations, and long-term QOL in patients who have had a first-time stroke. Written informed consent was obtained from all patients prior to inclusion in the study, and the study protocols were approved by the ethics committee of each hospital (IRB No. 2012-06-016 of Samsung Medical Center). The detailed rationale and protocols of the KOSCO study were described in a previous article [13,14].

All consecutive patients with an acute first-ever stroke who were admitted to representative hospitals from August 2012 to May 2015 were recruited to participate in the study. The inclusion criteria were as follows; 1) first-ever acute stroke (ischemic or hemorrhagic) with corresponding lesion and/or evidence of acute arterial occlusion on computed tomography

(angiography) or magnetic resonance imaging/angiography scan, 2) age ≥ 19 years at onset of stroke, and 3) onset of symptoms within seven days prior to enrollment. Patients with any of the following criteria were excluded from this study; 1) transient ischemic attack, 2) history of previous stroke, 3) traumatic intracerebral hemorrhage, and 4) foreign patients.

Baseline demographics and clinical characteristics of participants were assessed using a structured questionnaire and review of medical records during the first admission. Survey items included demographic data, and the presence of cerebrovascular risk factors were evaluated using standardized, structured questionnaires. The items were classified according to the current guidelines from the American Heart Association [15]. The demographic and cerebrovascular risk factors included in this analysis were; age, sex, education level, hypertension, diabetes mellitus, coronary heart disease, atrial fibrillation, family history of stroke, smoking, and alcohol intake. Anthropometric data, including height (cm) and body weight (kg), were measured after admission. Body mass index (BMI) was calculated as body weight (kg) divided by the square of height (m) (kg/m^2). To determine obesity, we used World Health Organization Regional Office for the Western Pacific Region criteria for obesity (BMI $\geq 25 \text{ kg}/\text{m}^2$) [16].

Assessment of ADL

Functional evaluations were performed by face-to-face functional assessment. To maintain optimum validity and interrater reliability, all assessments were performed by qualified evaluators who were licensed occupational or physical therapists and completed the standard training program provided by the KOSCO study. The Korean version of Modified Barthel Index (K-MBI) was used to assess ADL in stroke patients at 6 months and 1 year after stroke onset. The K-MBI is a Korean translated version of the Modified Barthel Index, and its validity and reliability has been demonstrated [17-19]. The K-MBI consists of 10 items of ADL: presence or absence of fecal or urinary incontinence, help needed for grooming, toilet use, feeding, transfers (e.g., from chair to bed), walking, dressing, climbing stairs, and bathing. The contents of test items were revised to reflect the Korean culture and lifestyle. Each activity is assigned a numeric value according to the patient's requirement for assistance (fully independent, minimal help required, moderate help required, attempts task but unsafe, unable to perform task). The maximum score of 100 demonstrates that the patient is fully independent with regard to physical functioning, whereas the lowest score of 0 represents a totally dependent state.

Patients were classified into 4 disability levels base on the K-MBI scores at 6 months: total dependency (K-MBI scores from 5 to 20), severe dependency (K-MBI scores from 21 to 60), moderate dependency (K-MBI scores from 61 to 90), or slight dependency (K-MBI scores from 91 to 95) [18]. Patients were additionally categorized into 3 groups according to changes in the K-MBI scores (Δ K-MBI) from 6 months to 1 year: the 1) improved group (IG), with an increase of 5 points or more ($5 \leq \Delta$ K-MBI); 2) stationary group (SG), with changes ranging from -4 to +4 points ($-4 \leq \Delta$ K-MBI ≤ 4); or 3) declined group (DG), with a decrease of 5 points or more ($-5 \geq \Delta$ K-MBI). Patients with the K-MBI scores above 95 or below 5 were excluded from this study, because the criteria of “increased 5 points or more” and “decreased 5 points or more” could not be applied.

Functional, QOL, and depression assessment parameters

At 6 months after stroke onset, a face-to-face functional assessment was performed. Assessments included the Fugl-Meyer Assessment (FMA) for motor function, the Functional

Ambulatory Category (FAC) for mobility and gait, the Korean Mini-Mental State Examination (K-MMSE) for cognitive function, the Korean version of the Frenchay Aphasia Screening Test (K-FAST) for language function, and the American Speech-Language-Hearing Association National Outcome Measurement System Swallowing Scale (ASHA-NOMS) for swallowing function. Also, patients completed structured, self-administered questionnaires and underwent a face-to-face interview for evaluation of QOL, using the Euro Quality of Life Five Dimension Scale (EQ-5D), and depression, using the Geriatric Depression Scale-Short Form (GDS-SF).

Statistical analysis

Descriptive statistics were applied to evaluate significant differences in the demographics and clinical characteristics of the patients. Linear-by-linear association were used to demonstrate changes in the proportion of improved, stationary and DG at different disability levels according to the K-MBI score at 6 months. Because the data did not satisfy the normal distribution assumptions, Wilcoxon signed rank test were used to assess the presence of significant differences between 6-month and 12-month K-MBI score in the IG, SG, and DG at each disability level. The Kruskal-Wallis test was applied to examine significant differences among the IG, SG, and DG at each disability level at 6-months and 1 year. A post hoc analysis was performed for pairwise comparison of the IG, SG, and DG using the Mann-Whitney U test via the Bonferroni procedure.

To define the influencing factors for functional recovery after 6 months to 1 year, participants were divided into 3 groups according to the changes of the K-MBI scores between 6 months and 1 year (Δ K-MBI); the DG if Δ K-MBI ≤ -5 , the SG if $-4 \leq \Delta$ K-MBI $\leq +4$, and the IG if Δ K-MBI $\geq +5$. The chi-square test was conducted to detect the association between the nominal scales and Δ K-MBI categories. The nominal factors included sex, risk factors such as hypertension, diabetes, coronary heart disease, atrial fibrillation, hyperlipidemia, obesity, and family history of stroke. In addition, Spearman's rank correlation test was performed to analyze the relationship between Δ K-MBI and ordinal scales such as age and functional parameters. Functional parameters included FMA, FAC, K-MMSE, K-FAST, ASHA-NOMS, EQ-5D, and GDS-SF scores. The potentially influential factors with a 2-sided univariate p value < 0.2 were selected for multivariate analysis. Finally, multivariate ordinal logistic regression analysis with the potentially influential factors was performed to identify the independently influencing factors on Δ K-MBI. All statistical analysis was performed using SPSS for Windows version 24.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Demographic and clinical characteristics of the study population

A total of 10,636 stroke patients were screened. And 8,210 patients with ischemic stroke were included, whereas 2,426 patients with hemorrhagic stroke were excluded. At the 6-month follow-up, 1,877 patients declined to participate and 480 patients died. A total of 5,384 stroke patients completed 6 months of follow-up, and 469 patients who lost follow-up were excluded. Of these patients, 1,265 patients with the K-MBI scores ranging from 5 to 95 at 6 months were included; 2,564 patients with the K-MBI scores above 95 or below 5 were excluded. Finally, 1,011 patients who were assessed at 1 year follow up survey were analyzed (Fig. 1). Demographic and clinical characteristics of participants are summarized in Table 1.

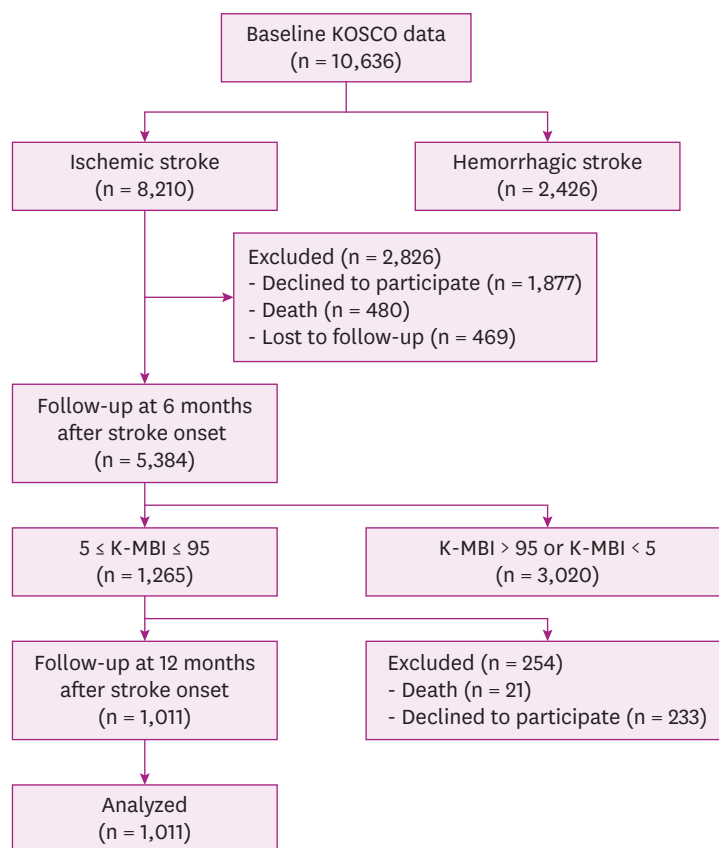


Fig. 1. Flow diagram of the study population.

KOSCO, Korean Stroke Cohort for Functioning and Rehabilitation; K-MBI, Korean version of Modified Barthel Index.

Table 1. Demographic and clinical characteristics of participants

Characteristics	Participants (n = 1,011)
Age (yr)	65.5 ± 13.6
Sex, male	584 (57.8)
BMI	23.4 ± 3.3
Education (yr)	9.0 ± 4.5
Medical history	
Hypertension, yes	637 (63.0)
Diabetes mellitus, yes	295 (29.2)
Coronary heart disease, yes	80 (7.9)
Atrial fibrillation, yes	136 (13.5)
Hyperlipidemia, yes	163 (16.1)
Obesity, yes	138 (13.6)
Family history, yes	93 (9.2)
Smoking, current	232 (23.4)
Alcohol, current	319 (31.6)
Stroke subtype	
Large-artery atherosclerosis	479 (47.4)
Small vessel occlusion	243 (24.0)
Cardioembolism	119 (11.8)
Other determined	70 (6.9)
Undetermined ischemic stroke	100 (9.8)

Values are presented mean ± standard deviation or number (%).
BMI, body mass index.

Proportion of disability levels

At 6 months after stroke onset, the proportions of patients with slight dependency, moderate dependency, severe dependency, and total dependency according to their K-MBI score category were 21.4%, 47.2%, 23.3%, and 8.1%, respectively. At 1 year after onset, the proportions changed to 36.9%, 34.5%, 19.2%, and 9.4%, respectively.

Changes in the K-MBI score between 6 months and 1 year

Mean K-MBI scores across all patients at 6 months and 1 year were 68.6 ± 25.4 (mean \pm standard deviation) and 71.8 ± 29.3 , respectively. The difference between mean 6 months and 1 year K-MBI scores was significant ($p < 0.001$). Mean K-MBI scores at each disability level and subgroup according to change in the K-MBI score was analyzed (Fig. 2). The IG and DG showed significant differences in 6-month and 1 year K-MBI scores at all disability levels. The SG showed a significant difference only in the slight dependency and moderate dependency subgroups (Supplementary Table 1). The mean K-MBI scores of the IG, SG, and DG were

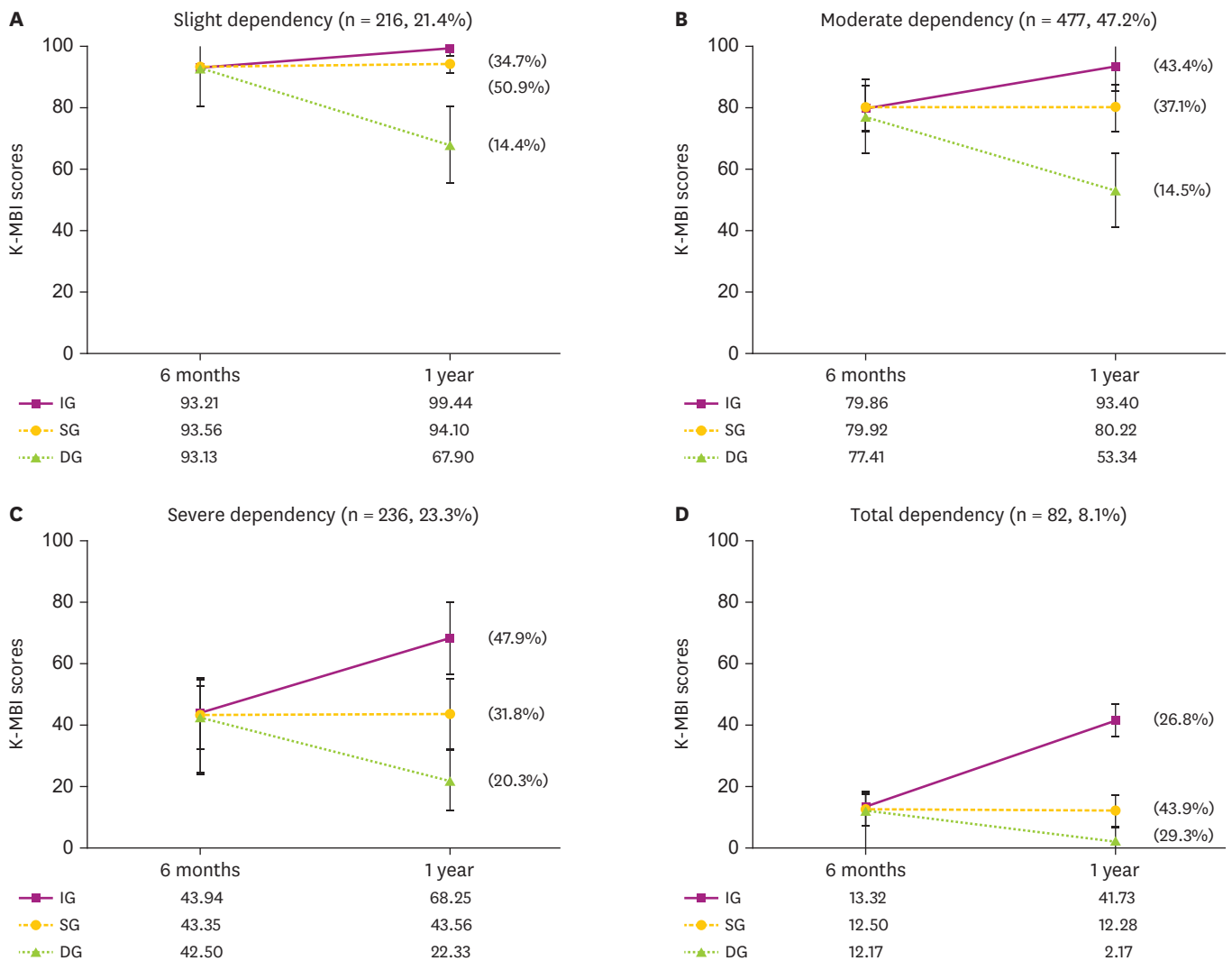


Fig. 2. Changes in the K-MBI score from 6 months to 1 year among the disability levels. The improved group, stationary group, and declined group did not show significant differences in the K-MBI scores at 6 months after stroke onset, but did show significant difference in the K-MBI scores at 1 year after onset at all disability levels.

K-MBI, Korean version of Modified Barthel Index; IG, improved group; SG, stationary group; DG, declined group.

* $p < 0.05$.

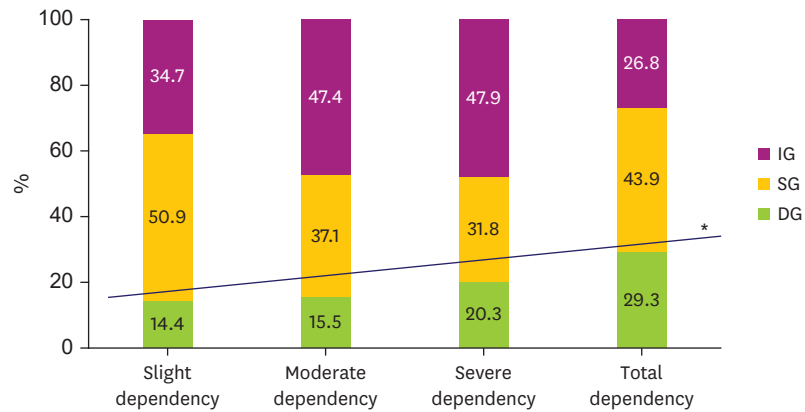


Fig. 3. Proportions of patients in the improved, stationary, and declined group at given disability level 6 months after onset. The graph shows significantly positive linear association of declined group in patients with severer dependency.

IG, improved group; SG, stationary group; DG, declined group.

*p for trend = 0.002.

not significantly different at 6 months. However, they were significantly different from one another at all disability levels at 1 year.

Overall, 43.1% of patients belonged to the IG, 39.4% to the SG, and 17.5% to the DG. Linear-by-linear association revealed a significant increase of the DG in patients whose K-MBI score represented severer dependency ($p = 0.002$) (Fig. 3).

Influencing factors for functional recovery after 6 months

The influencing factors for changes in the K-MBI score between 6 months and 1 year are described in Table 2. In univariate analysis, coronary heart disease, obesity, family history of stroke, and FMA, FAC, K-MMSE, K-FAST, ASHA-NOMS, EQ-5D, GDS-SF scores at 6 months were significant relating factors for changes in the K-MBI score. In multivariate ordinal logistic regression analysis, only obesity and GDS-SF were significant independent influencing factors for changes in the K-MBI scores. Obesity showed a positive influence ($\beta = 0.365$, $p = 0.047$) and GDS-SF showed a negative influence ($\beta = -0.034$, $p = 0.010$).

Table 2. Factors associated with improvement in the K-MBI scores from 6 months to 1 year after stroke onset

Factors	Univariate p value	Multivariate p value	β
Risk factors			
Coronary heart disease	0.132	0.322	-0.195
Obesity	0.001	0.047*	0.365
Family history	0.070	0.977	-0.006
Function, QOL, and depression parameters (at 6 mon)			
FMA	< 0.001	0.168	0.003
FAC	0.001	0.557	-0.031
K-MMSE	< 0.001	0.172	0.019
K-FAST	< 0.001	0.340	-0.010
ASHA-NOMS	0.003	0.322	0.063
EQ-5D	0.001	0.860	0.047
GDS-SF	< 0.001	0.010*	-0.034

K-MBI, Korean version of Modified Barthel Index; QOL, quality of life; FMA, Fugl-Meyer Assessment; FAC, Functional Ambulatory Category; K-MMSE, Korean Mini-Mental State Examination; K-FAST, Korean version of Frenchay Aphasia Screening Test; ASHA-NOMS, American Speech-Language-Hearing Association National Outcome Measurement System Swallowing Scale; EQ-5D, Euro Quality of Life Five Dimension Scale; GDS-SF, Geriatric Depression Scale-Short Form.

*p < 0.05.

DISCUSSION

Independence with regard to ADL is a vitally important outcome for stroke survivors. Studies about the time course of functional recovery in stroke patients have accumulated over recent years. The majority of authors agree that most functional recovery occurs in first month after stroke onset and reaches a plateau within 6 months; however, several recent studies have suggested that recovery can continue for up to one year [20]. In this study, the mean K-MBI score across all patients was 68.6 at 6 months and 71.8 at 1 year after stroke onset. The mean K-MBI scores at 6 months and 1 year were significantly different, but the difference was only 3.2 points. Although a slight increase in the K-MBI score may have substantial meaning to both clinicians and patients, a statistically significant difference does not necessarily mean a clinically important difference. In a previous study by Hsieh et al. [21], reported that the minimal clinically important difference (MCID) detected with Barthel Index (BI) was estimated to be 1.85 points on a 0 to 20 scale. They suggested that if the mean improvement in BI score within a stroke group is less than the MCID of 1.85 points, even if the change in score has reached a statistically significant level ($p < 0.05$), it should not be considered to be important. Because the BI has the same items as the K-MBI, and the BI score range is one-fifth of the K-MBI score range, the MCID of the K-MBI can be estimated by multiplying 1.85 by 5, which is 9.25 points. Consequently, a mean change in the K-MBI score of 3.2 points between 6 months to 1 year may not represent a clinically important difference. On the other hand, the change in mean K-MBI score in all IG and DG was greater than 9.25 points, except in the improved patient subgroup with slight dependency for ADL. Hence, although the overall change in mean K-MBI score between 6 months and 1 year in this study may not seem to be different from a clinical point of view, when study participants were categorized according to disability level and functional changes, more than half of the patients' K-MBI score had changed significantly. This finding is consistent with a previous report by Kwakkel et al. [22], which showed that, at the overall group level, no statistical improvement in functional independence occurred from 6 months after stroke onset onward; while at an individual level, 10.4% of patients showed significant improvement or deterioration in ADL dependency as measured with the BI. In the same context, a significant difference was even noticed in the stationary subgroups with slight dependency and moderate dependency for ADL as a consequence of the large sample sizes.

Another important finding of this study is that the proportion of patients in the DG showed a significantly increasing trend at more severe disability levels. This indicates that patients with more severe disability at 6 months after stroke onset have a higher risk of decreasing in functional independence afterward. The BI score in the early phase or at discharge is known to be a strong predictor for long-term functional outcome [23,24]. To the best of our knowledge, this is a first study to address that functional outcomes at 6 months after stroke onset can be useful information for the prediction of functional decline after 6 months. Our results suggest that patients with low functional outcomes at 6 months need careful follow-up to prevent further deterioration at 1 year.

In this study, the influencing factors for functional recovery after 6 months were identified as obesity and depression. These factors have been previously known to be associated with functional recovery in stroke patients. Obesity is a well-established risk factor for stroke, and weight reduction is recommended in the obese population to reduce stroke risk. However, obese patients who experience stroke seem to have lower mortality and recurrence rates compared to non-obese patients [25-27]. Obesity is also known to be a good predictor of

functional recovery in patients with both ischemic and hemorrhagic stroke [28-30]. A recent article from the KOSCO study reported that extreme obesity ($30 \leq \text{BMI}$) was a predictor of good functional outcomes at 6 months after stroke onset in elderly patients [30]. In line with our previous report, this study revealed the effect of obesity on functional improvement between 6 months and 1 year after stroke. Differences between our previous study and current report include that, in this study, we dichotomized obese and non-obese patients using a cutoff BMI value of 25, and our results showed that obesity affected functional recovery regardless of age. The novel finding from our study is that, while previous studies analyzed functional outcome scores at a specific time point, we examined the effect of obesity on the change in the K-MBI score between 6 months and 1 year. This can make a difference when predicting functional recovery in stroke patients. Based on our results, we can conclude that obese patients have higher chance of functional recovery even after 6 months after stroke onset.

Interesting features from our study include that assessment of functional, QOL, and depression status at 6 months were included for analysis, instead of acute phase status. Early prognostic factors are already well identified, and only a few interventions are applicable for modification of these factors. We hypothesized that, if some portion of functional, QOL, and/or depression status at 6 months after stroke onset has a significant influence on functional recovery after 6 months, efforts to improve these parameters before the 6-month mark may enhance functional recovery afterward. In univariate analysis, all functional, QOL, and depression parameters were significant; however, in multivariate analysis, GDS-SF score was the only parameter with significant influence on ADL recovery after 6 months. Although the GDS-SF is not the gold standard for the diagnosis of poststroke depression, it has been identified as an efficient self-rating screening tool for poststroke depressive symptoms [31]. Depression is an important and common complication of stroke, with reported frequencies ranging from 10% to 40% [32,33]. Several studies have shown that not only poststroke major depression, but also mild depression or even depressive symptoms has a negative influence on the functional recovery of patients after stroke [34,35]. It has also been reported that remission of poststroke depression during the first few months after stroke was associated with significantly greater improvement in ADL function than continued depression [36]. The findings from our study demonstrating that patients with a higher GDS-SF score 6 months after stroke also have a higher risk of functional deterioration after 6 months are consistent with this prior research. The underlying mechanism is unclear; however, we can hypothesize that treating depressive symptoms in the subacute phase after stroke may reduce GDS-SF score at 6 months, which may help the functional recovery of patients, or at least prevent their deterioration, after 6 months.

There are 2 limitations to this study. We acknowledge that the K-MBI instruments might not be proper to assess instrumental ADL; therefore, tasks that are not measured with the MBI may still play an important role in determining disability after stroke. In addition, the BI, on which the K-MBI is based, is known for its ceiling effect, that is, its inability to detect functional improvement in patients with the K-MBI score of 100 [37]. The K-MBI is a scale commonly used to comprehensively determine the functional independence, but the subscales can be used for assessing specific areas such as mobility or upper limb function. In this study, we only used changes in the total K-MBI score but not subscale changes in detail. This may explain why the IG with a slight dependency for ADL failed to show a clinically important difference in the MBI score between 6 months to 1 year. This group's K-MBI score at 1 year was 99.4, which is almost the top of the K-MBI scale. Therefore, patients in the IG might have shown further improvement, but the K-MBI instruments were not able to

detect changes beyond their scales. A previous article pointed out that the commonly held belief in the medical community about stroke recovery that limits meaningful recovery to 6 months may be a consequence of using an insensitive system of measurement [20]. This may be applicable to situations in which the K-MBI is used for ADL measurement in patients with slight dependency; however, with our results, the K-MBI successfully demonstrated its validity in detecting meaningful functional changes in patients with moderate to total dependency. Another limitation is that height and weight were measured only once after admission. Therefore, we do not have information about changes in BMI, which has also been suggested as an important factor for stroke mortality [38]. Finally, the functional recovery pattern may vary depending on the stroke lesion. Therefore, subgroup analysis based on different brain lesions may provide more insight into long term recovery pattern after stroke and have a worth for future study. On the basis of this longitudinal study, 3 important findings should be addressed. First, functional recovery, as measured by ADL independency, changed in various directions even after 6 months from stroke onset. Second, patients with more severe dependency at 6 months after stroke onset had a higher risk of experiencing decline in functional independence afterward. Last, obesity and depression were influencing factors on functional recovery after 6 months following stroke onset; obesity showed a positive influence, while depression showed a negative influence.

SUPPLEMENTARY MATERIAL

Supplementary Table 1

Changes in the K-MBI scores at given disability levels from 6 months to 1 year

[Click here to view](#)

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