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ORIGINAL ARTICLE

Structural Modeling of Early Ambulation Progression in Patients with Acute Stroke: A Covariance Structure Analysis Approach

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Objectives: This study used structural equation modeling (SEM) to elucidate the causal relationships between Functional Independence Measure (FIM) items and consciousness levels in patients with stroke and low consciousness levels 2 weeks after initiating occupational therapy (OT). This modeling sought to identify the factors influencing the number of days required to get out of bed. **Methods:** SEM was used for multifactorial simultaneous analysis in a study of 22 patients with a Japan Coma Scale score of 20 after stroke. The Glasgow Coma Scale was used to evaluate patients' consciousness level; FIMs were used to evaluate activities of daily living in the ward. Influencing factors, including "bed/chair transfers" and "toilet transfers," were defined as "transfer functions," while factors involving "social interactions," "comprehension," "memory," "problem solving," and "expression" were defined as "cognitive decline." **Results:** After 2 weeks, standardized coefficients showed that "transfer functions" and "cognitive decline" had effects of –0.33 and –0.25, respectively, on "early ambulation days." Further analysis revealed that improvements in "consciousness level" impacted "early ambulation days," with coefficients of –0.35 for "transfer functions" and 0.14 for "cognitive decline." Through the "consciousness level" observation variable, the coefficients of indirect effects were –0.27 for "transfer function" on "days to get out of bed," 0.38 for "cognitive decline," and –0.06 for "self-care" on "early ambulation days." **Conclusions:** Improvement in transfer movements and cognitive decline influenced the number of days required to get out of bed without improving consciousness or affecting early ambulation.

Key Words: cognition; consciousness; functional independence

INTRODUCTION

The effectiveness of early rehabilitation in patients with stroke in the acute phase has been reported.[1–6] In the acute phase, vital signs such as consciousness and blood pressure are unstable, necessitating effective risk management against recurrence. Interventions involving physical therapy (PT), occupational therapy (OT), and speech therapy (ST) are crucial for safe and efficient rehabilitation in the acute phase.[7,8] Collaboration by rehabilitation specialists in PT, OT, and ST is crucial for team-based care.

Acute phase rehabilitation is essential, even in patients with a low level of consciousness after stroke onset. Early mobilization is also reported to enhance recovery.[6,9–11] Indredavik et al.[9] reported that early ambulation resulted in significantly less variability in blood pressure. In a comparison of early and delayed intervention, Tanaka et al.[10] compared a group of 34 patients with stroke who could sit up early and a group of 21 patients with stroke who received sitting training within 7–14 days of stroke onset. Using the Functional Independence Measure (FIM) and Stroke Impairment Assessment Set, they found that the motor FIM score in the early group was significantly higher.[10] Active rehabilitation, such as sitting, standing, and transferring movements after stroke onset, reportedly affects general condition and motor function.

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Table 1. Participant characteristics and passage of time (n = 22)

Item	Commencement of OT	Two weeks after commencement of OT
Disease		
Cerebral hemorrhage	16	
Cerebral infarction	6	
Average age, years	73.1 (67–87)	
Sex (M/F)	18/4	
Location of brain damage (R/L)	15/7	
Days of early ambulation, days	3.0 (2.0–5.0)	11.0 (9.0–12.0)
Length of stay, days	1 (1–4)	15.0 (15.0–18.0)
FIM		
Motor	15.0 (13.0–17.0)	16.0 (15.0–21.0)
Cognitive	11.1 (9.0–12.0)	13.0 (12.0–14.0)
Total	26.0 (22.0–29.0)	29.0 (27.0–35.5)
GCS	12 (11–12.5)	13 (12–13)

Data given as number or median (IQR).

However, determining the appropriate time for patients with low levels of consciousness to get out of bed poses significant challenges.[12] In some cases, the application of an OT approach is difficult. Some studies have emphasized the importance of active mobilization over consciousness arousal in such patients.[13–15] Consciousness levels persisting at a Japan Coma Scale (JCS) score of 20 for an extended period after initiating OT make treatment decisions particularly complex. This complexity arises from the ambiguity in prioritizing motor functions of getting out of bed or focusing on arousal, which more effectively reduces the number of days required to get out of bed. Furthermore, few studies have examined the factors and causal relationships that affect all FIM items and the number of days to get out of bed in patients with a JCS score of 20. Therefore, this study aimed to analyze the factors influencing the number of days required to get out of bed in such patients and develop a factor structure model. The study employed covariance structure analysis and structural equation modeling (SEM) as statistical methods to verify the causal relationships between these factors.[16] SEM facilitates visual elucidation of the relationships between variables and verifies the connections between latent variables by treating multiple observed variables as latent.

The novelty of this study lies in providing new insights into the factors influencing the duration until ambulation and their relative importance. The findings of this study are intended to assist other clinical professionals in reducing the level of assistance required for managing cognitive decline and enhancing transfer movements during OT and ward care.

MATERIALS AND METHODS

Study Design

This study employed a single-center, prospective cohort design to investigate the factors affecting the number of days until mobilization in patients with a low level of consciousness.

Study Participants and Sample Size

The study included 22 patients (18 men and 4 women) diagnosed with stroke in Hospital A who were prescribed OT. Although the participants could understand the instructions, they had a decreased level of consciousness (JCS score of 20) (**Table 1**). The exclusion criteria were JCS Digit I and III, recurrence of cerebral hemorrhage, subarachnoid hemorrhage, and requirement of bed rest for 7 days or more for medical reasons. Among the patients, 16 had cerebral hemorrhage and 6 had cerebral infarction. A total of 15 patients had damage to the right brain, whereas 7 had damage to the left brain. The data collection period was from April 2019 to March 2020. The mean age (interquartile range, IQR) of the participants was 73.1 (67–87) years. The median number of days from the date of admission to the commencement of OT was 1 (1–4) day. The median number of days from the day of admission to the beginning of getting out of bed was 3.0 (2.0–5.0) days. This study considered age, disease, level of consciousness, and days to mobilization to address potential sources of bias.

Procedure Definitions

Recovery from illness involves a series of stages that lead to independence in activities of daily living (ADL), such as sitting, standing, and walking.[17] Owing to the lack of standardized definitions for "getting out of bed" in the existing literature,[18] in this study, it was defined as the point when a physician permitted a patient to be transferred to a wheelchair, regardless of consciousness impairment. The time from awakening to getting out of bed was recorded as "days out of bed." The criteria for initiating this process at Hospital A were adapted from Hara's guidelines for early mobilization post-stroke.[19] Risk management during rehabilitation adhered to Anderson's criteria,[20] with physician instructions customized to individual patient conditions.

Assessments of the time of getting out of bed, type of exercises performed, and evaluation methods were based on the protocols by Bernhardt et al.[21] The intervention period involved simultaneous physiotherapy and ST for all cases, starting immediately and continuing for 2 weeks. The procedures included monitoring blood pressure fluctuations during rest, checking muscle activity, and confirming whether activities such as sitting at the edge of the bed and standing up were possible. Over 2 days, the patients got out of bed and participated in 40-min rehabilitation exercises in the ward training room on the same floor, involving PT, OT, and ST. PT focused on neuromuscular re-education for paralyzed limbs, respiratory rehabilitation, limb stretching, and sitting exercises. After getting out of bed, emphasis was placed on practicing fundamental movements such as active getting out of bed, turning over, sitting up, and walking. ST concentrated on oral care and swallowing function, incorporating advanced cognitive exercises as consciousness improved. OT also engaged in neuromuscular re-education, exercises for paralyzed limbs, limb stretching, and sitting exercises while in bed, progressing to active reach movement exercises mediated through activities after getting out of bed. Both PT and OT utilized open-back sitting to enhance arousal. Although the starting criteria for sitting exercises were generally based on those devised by Hayashida et al.,[22] they were modified in our hospital to include patients with a JCS score of 20 or lower, as deemed appropriate by the attending physician.

Evaluation Endpoints

Study endpoints were defined as the number of days out of bed; number of days in the hospital; total score of consciousness level using the Glasgow Coma Scale (GCS) at the commencement of OT and 2 weeks after the commencement of OT; and the FIM item and total scores. GCS was used instead of JCS to evaluate the level of consciousness in detail. The evaluators included a physical therapist, an occupational therapist, and a speech pathologist who were unaware of the purpose of the study. The FIM[10,23] is a widely used index in stroke prognosis prediction and program development; it is highly reliable and valid.

Analysis Method

This study aimed to use SEM to elucidate the causal relationship between FIM items and consciousness levels in patients with stroke and low consciousness levels for 2 weeks. Covariance structure analysis was used to explore causal relationships among defined factors. Observable variables, latent variables, and indirect effects were analyzed. The Goodness of Fit Index (GFI), Adjusted GFI (AGFI), Comparative Fit Index (CFI), and Root Mean Square Error of Approximation (RMSEA) were used to fit the model. GFI is a measure of how well the model explains the covariance of data. A GFI score greater than 0.9 is considered to indicate a good fit of the data.[16,24] The AGFI is an index that adjusts GFI with degrees of freedom. Furthermore, the closer it is to 1, the better the fit to the data.[16] The CFI is a criterion-based index that compares the goodness of fit between the independent and analytical models. It is also a goodness of fit index that considers the influence of degrees of freedom. The CFI is scaled between 0 and 1, with values closer to 1 interpreted as a better fit.[24] In this study, the indices that did not depend on degrees of freedom were included in the indices of goodness of fit because the number of samples was limited. RMSEA is an indicator of the amount of deviation between the model and the optimal distributions per degree of freedom. A score of 0.1 or greater was judged as poor.[25] The strength of the relationship between the variables was determined using the standardized estimated value (path coefficient).[24]

Figure 1 shows the analytical procedure used in this study. Factor analysis was performed for FIM items and days out of bed. A causal hypothesis model was created based on the results of the factor analysis, and simultaneous analysis was performed using SEM as a hypothetical model. The sample validity for exploratory factor analysis (EFA) was confirmed using the Kaiser–Meyer–Olkin (KMO) measure and Bartlett's sphericity test. Simultaneous analyses were performed using SEM on covariance data. Statistical analyses were carried out using IBM SPSS Amos 19.0 (Stats Guild, Japan), with the significance level set at $P<0.05$.

This study was conducted in compliance with ethical

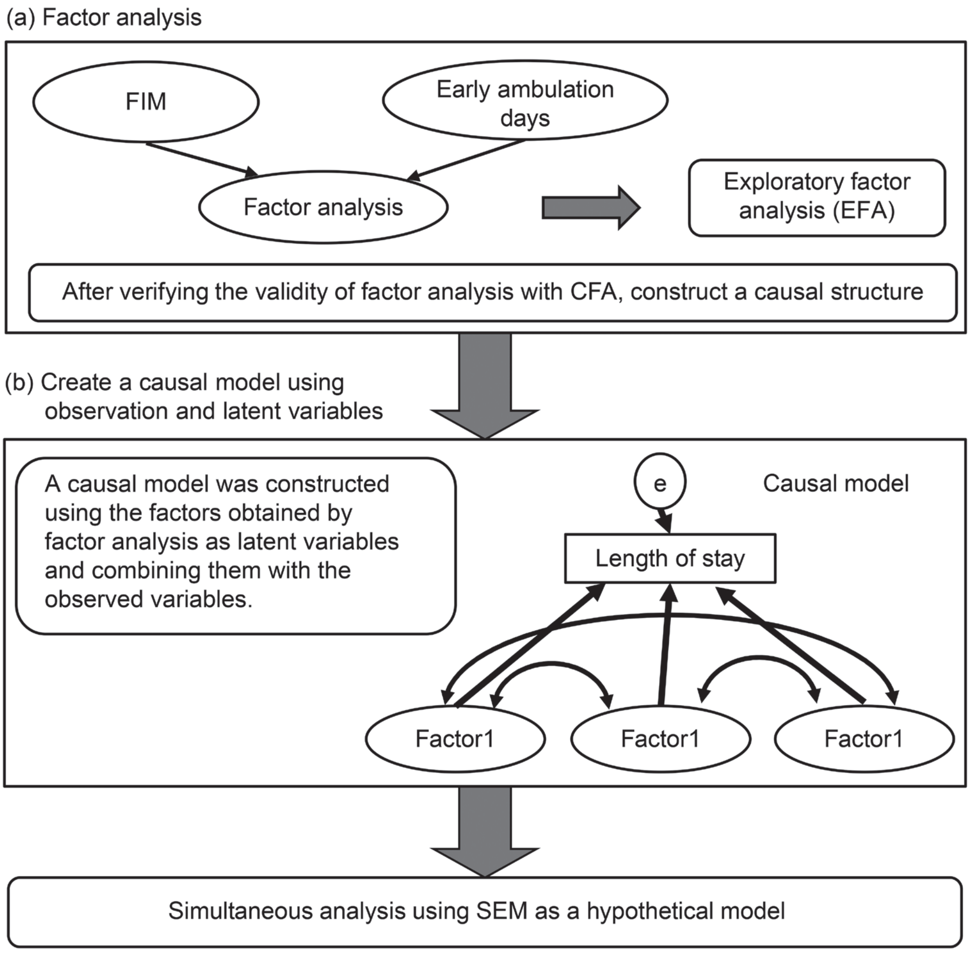

Fig. 1. Flowchart of the analytical procedure. (a) EFA was performed on FIM items and the number of days out of bed. The validity of the EFA results was confirmed using CFA. (b) Latent variables were identified based on the analysis results and a causal hypothesis model was constructed using observed and latent variables. Simultaneous analysis can be performed using SEM as a hypothetical model.

norms following the Declaration of Helsinki and relevant laws protecting personal information. Written consent was obtained from all participants; the study was approved by the Ethics Committee of Kansai University of Welfare Science (approval number: 17–60).

RESULTS

Participant Characteristics

The patient characteristics are presented in **Table 1**. The median number of days out of bed was 11.0 (9.0–12.0) days. The median number of days of hospitalization 2 weeks after the commencement of OT was 15.0 (15.0–18.0) days. The FIM total score at the start of OT was 26.0 (22.0–29.0). After 2 weeks, this score was 29.0 (27.0–35.5). The consciousness level at the start of OT was 12 (11–12.5); after 2 weeks, the score was 13 (12–13).

Factor Analysis Result

The KMO measure of sample adequacy was 0.662. Furthermore, Bartlett's sphericity test score was 0.000. Therefore, the validity of the sample was confirmed.

The first factor consisted of "social interactions," "comprehension," "memory," "problem solving," and "expression" and was defined as "cognitive decline"; the associations were 0.91, 0.96, 0.96, 0.98, and 0.85, respectively (**Table 2**). The second factor consisted of "eating" and "toileting" and was defined as "self-care," with respective relevance of 0.93 and 0.96. The third factor consisted of "toilet transfers" and "bed/chair transfers" and was defined as "transfer function,"

Table 2. Factor analysis two weeks after the start of OT

	Latent variable		
	Cognitive function	Self-care	Transfer functions
Toilet transfers	0.199	0.269	0.839
Bed/chair transfers	0.150	0.267	0.977
Social interactions	0.914	0.069	0.219
Comprehension	0.964	0.005	0.228
Memory	0.964	0.001	0.128
Problem solving	0.983	−0.028	0.270
Expression	0.847	−0.276	0.020
Eating	−0.026	0.934	0.214
Toileting	−0.055	0.964	0.356

The latent variable was set to factor 1 for the transfer function, 2 for cognitive function, and 3 for self-care.

with associations of 0.84 and 0.98, respectively. Confirmatory factor analysis (CFA) was performed based on the results of the EFA. The GFI, AGFI, and RMSEA scores were 0.825, 0.753, and 0.047, respectively. Therefore, the degree of conformity was confirmed to be within the allowable range. Consequently, the EFA results were adopted.

Examination of SEM Results: Direct Effect at 2 weeks

SEM was performed on a hypothetical model in which the latent variables of “transfer function,” “cognitive decline,” and “self-care,” obtained from the results of factor analysis, affect the “number of days out of bed.” Consequently, the goodness of fit indices for this causal model were $\chi^2=39.742$ ($P=0.163$), GFI=0.773, AGFI=0.610, CFI=0.736, and RMSEA=0.083. Therefore, it was confirmed that the results of this study were within a certain allowable range. The standardized coefficient indicating the direct effect of the latent variable “transfer function” on the observed variable “number of days out of bed” was −0.33 (**Fig. 2**), that of the latent variable “cognitive decline” on “number of days out of bed” was −0.25, and that of the latent variable “self-care” on “number of days out of bed” was 0.05.

Examination of SEM Results: Indirect Effect after 2 weeks

Three latent variables influenced “days out of bed” through “consciousness level.” SEM analysis was performed using a hypothetical model. Consequently, the fitness indices for this causal model were $\chi^2=42.960$ ($P=0.267$), GFI=0.777, AGFI=0.612, CFI=0.819, and RMSEA=0.061. The goodness of fit index was within a certain allowable range. The standardized coefficient indicating the direct effect of “transfer function” on the observed variable “number of days out of bed” was −0.35 (**Fig. 3**). The standardized coefficient indicating the direct effect of “cognitive decline” on the “number of days out of bed” was −0.14, and that of “self-care” on the “number of days out of bed” was 0.03. The standardized coefficient indicating the indirect effect of: “transfer function” through “consciousness level” on the “number of days out of bed” was −0.27, “transfer function” on “number of days out of bed” through “consciousness level” was −0.01, “cognitive decline” on “number of days out of bed” through “consciousness level” was 0.38, and “self-care” on “number of days out of bed” through “consciousness level” was −0.06.

DISCUSSION

Stroke treatment should prevent disuse syndrome and improve ADL and social rehabilitation at an early stage. Therefore, early and proactive comprehensive rehabilitation by physical, occupational, and speech therapists is recommended and should be performed under sufficient risk management.[1,17] Studenski et al.[25] observed that increasing PT, OT, and ST interventions improved ADL recovery in patients with stroke with mild-to-moderate motor impairments within 150 days of onset. Similarly, Kwakkel et al.[26] reported ADL recovery with increased PT, OT, and ST interventions within 30 days of stroke onset. These findings suggest that increasing the intensity of PT, OT, and ST interventions contributes to ADL recovery. However, the specific impact on consciousness levels and intervention methods remains unclear. Previously, Nakayama and Kimura[27] found that improving transfer function could reduce the number of days away

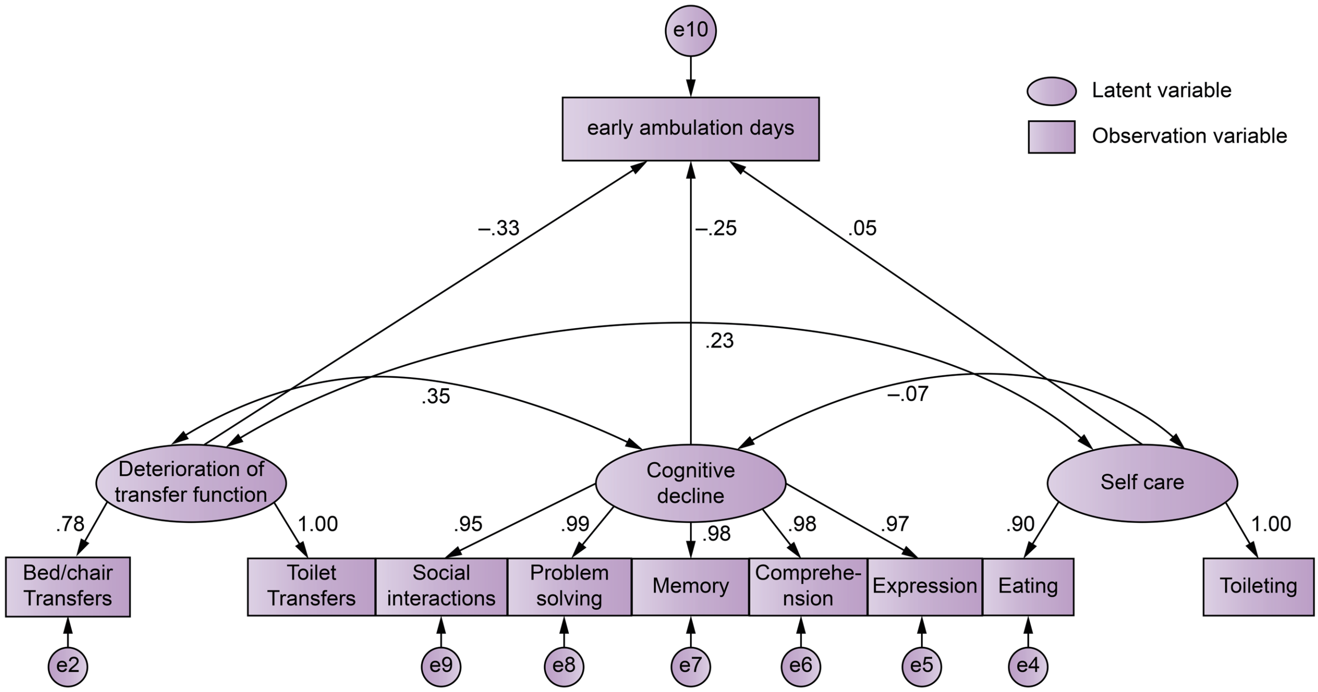

Fig. 2. Hypothetical model demonstrating the impact of latent variables on "early ambulation days" after 2 weeks. Deterioration in the transfer function has a significant negative effect on the number of days following early ambulation. Cognitive decline and self-care do not significantly influence the duration of early ambulation. The transfer function affects "bed/chair transfers" and "toilet transfers." Cognitive function affects "social interaction," "problem solving," "memory," "comprehension," and "expression." Self-care affects "eating" and "toileting." Goodness of fit indices: $\chi^2 = 39.742$ (P = 0.163), GFI = 0.773, CFI = 0.736, AGFI = 0.610, and RMSEA = 0.083.

from bed immediately after the start of OT. Furthermore, Bernhard et al.[28] reported that patients who started sitting or standing within 24 h after stroke onset required fewer days for ambulation and had a higher Barthel Index than patients who received regular rehabilitation. Therefore, the timing of early mobilization and the content of the approach may affect the subsequent goal, regardless of the consciousness level.

In contrast, some previous studies[13–15] on OT emphasized awakening rather than active mobilization. Therefore, selecting treatment in patients with a prolonged low level of consciousness may be difficult. In this study, similar to previous research, PT, OT, and ST interventions were provided on the same day. The present study aimed to address previous research issues by incorporating not only "days to mobilization" but also "consciousness level" as latent variables in the FIM items 2 weeks after the start of OT. The study investigated a new model using covariance structure analysis. Terasaka et al.[29] reported the importance of cognitive FIM after 2 weeks. Maintenance of functions, such as memory, motivation, and understanding judgment, is required to obtain a high score on the cognitive FIM. Therefore, those with high cognitive FIM scores strongly opt for rehabilitation and recovery. In addition, because their state of consciousness is good, obtaining the effect of motor learning is easy. Knowing cognitive FIM after 2 weeks is a major index for predicting motor FIM improvement, ADL, and home return.[27] Therefore, even if the functional impairment is severe, cases with high cognitive FIM scores at 2 weeks have a high possibility of improvement.[30] The results of this study support the importance of "cognitive decline" because it has a significant impact on "days out of bed." Furthermore, the model that influences "days out of bed" through "consciousness level" showed that improvement in "transfer function" and "cognitive decline" reduced the number of days out of bed, rather than reducing "days out of bed" with improvement in "consciousness level."

The effect of "self-care" on the "number of days out of bed" was low even after 2 weeks, similar to when OT was commenced. Clarifying the impact of self-care will serve as an indicator of the appropriate time to use FIM and change

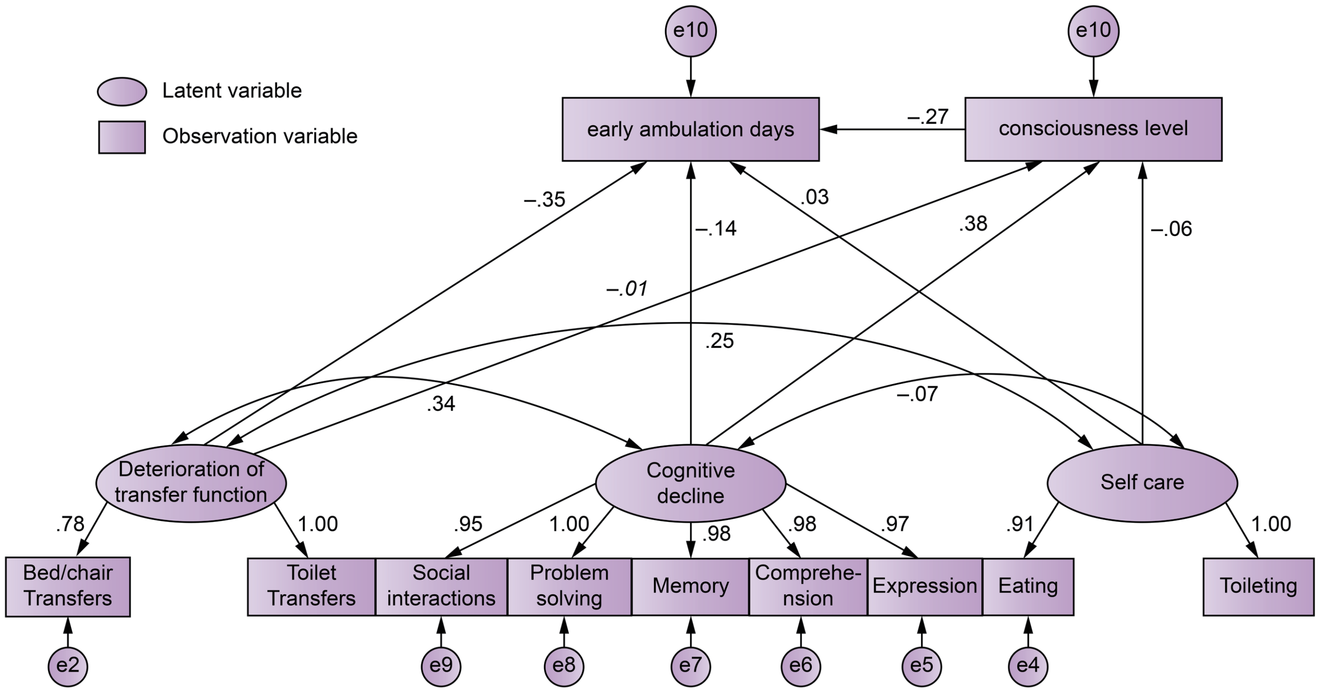

Fig. 3. Hypothetical model illustrating latent variables influencing the duration of "early ambulation days" via the mediating factor of "consciousness level" after 2 weeks. Deterioration in the transfer function has a significant negative effect on the number of days following early ambulation. Cognitive decline and self-care do not significantly affect the duration of early ambulation. The transfer function affects "bed/chair transfers" and "toilet transfers." Cognitive function affects "social interactions," "problem solving," "memory," "comprehension," and "expression." Self-care affects "eating" and "toileting." Goodness of fit indices: $\chi^2=42.960$ (P=0.267), CFI=0.819, GFI=0.777, AGFI=0.612, and RMSEA=0.061.

the approach.

Regarding OT, reaching tasks are performed with the aim of achieving specific movements. Executing purposeful movements requires the activation of intention and integration of cognitive information from the lower domain into working memory.[30] Engaging in occupational activities allows individuals to develop behavioral strategies and action plans based on their working memory of the task, which they then execute, adjust, and learn from. These activities are thought to be effective in activating not only the cerebral cortex association areas but also the neural circuits involving the basal ganglia and cerebellum, as well as the brainstem's postural control mechanisms.[31] Replacing purposeful movements with reaching tasks in OT may activate brain regions extending from the occipital lobe to the motor cortex, potentially leading to improved cognitive function.

The findings of this study suggest that improvements in "transfer function" and "cognitive decline" over a 2-week period can influence the "number of days out of bed." The factor structure developed in this study suggests that these improvements impact the "number of days out of bed" more significantly than changes in "consciousness level." The creation of this novel model could facilitate earlier initiation of OT. Furthermore, this model mirrors performance in ADL, making it beneficial for guiding other clinical professionals. It supports the reduction in assistance required for managing cognitive decline and enhancing transfer movements during OT sessions and throughout ward care.

Hayashi[32] stated that the study results obtained by observing the actual usage conditions in their natural state can be easily generalized to other groups and have high external validity. This study showed the factors affecting the number of days out of bed for a certain period in patients with acute stroke and prolonged low consciousness levels with a JCS score of 20. Furthermore, these were the results of a cohort study that analyzed the direct and indirect effects using SEM analysis and clarified the relationship. Therefore, it can be inferred that the scale is easy to generalize and has high external validity. The novelty of this study is that it suggests that improvements in "transfer function" and "cognitive function" after a 2-week period may influence the "number of days until ambulation." Furthermore, it indicated that improvements in "transfer function" and "cognitive function" on the FIM may have a greater impact on the "number of days until ambulation" than may have improvement in the "level of consciousness."

One limitation of this study is the restricted number of cases, because inclusion was limited to patients with a JCS score of 20 at admission. This restriction contributed to a large variability in the data and made it difficult to accurately reflect patient improvements in the FIM scores. Consequently, the fit of the factor structure model was insufficient. In addition, because factors inhibiting getting out of bed were analyzed using FIM scores, directly assessing the impact of early interventions in transfer function on reducing the "number of days out of bed" was difficult. Furthermore, this study did not attempt to standardize the number of days out of bed and the number of days of hospital stay 2 weeks after the commencement of OT. Therefore, suggesting that "consciousness level" has an insignificant effect on the "number of days out of bed" based only on this result is difficult. Undeniably, a mutual relationship exists. In the future, an inter-institutional study with related hospitals will help obtain a larger sample size and richer data. In addition, standardizing the disease and damaged area will ensure clearer understanding of the causes.

CONCLUSION

This study used SEM analysis in patients with stroke with prolonged low levels of consciousness. Using the SEM analysis, a factor structure model was constructed for the variables affecting the number of days to mobilization based on all FIM items and consciousness levels. The results suggest that improvements in transfer movements and cognitive items significantly affected the number of days to mobilization. Based on these results, improving cognitive items and transfer movements not only in rehabilitation settings but also in ward settings could be considered clinically meaningful.

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CONFLICTS OF INTEREST

The author declares no conflict of interest.

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