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ARTICLE

A prediction model of functional outcome at 6 months using clinical findings of a person with traumatic spinal cord injury at 1 month after injury

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Abstract

Study design Retrospective statistical analysis of database.

Objectives Prediction of the Spinal Cord Independence Measure version III Total Score (SCIM-TS) at 6 months after injury based on physical findings at 1 month after injury is an important index for rehabilitation approach in the recovery phase.

Setting Spinal Injuries Center, Fukuoka, Japan.

Methods The study participants were selected from patients with traumatic spinal cord injuries who were registered in the Japan Single Center Study for Spinal Cord Injury Data Base (JSSCI-DB) of the Japan Spinal Injuries Center specializing in spine and spinal cord injuries. Of the 534 participants registered with the JSSCI-DB between January 2012 and October 2018, we retrospectively extracted 137 participants for 6 months after injury, and these participants were included in this study.

Results According to multiple regression analysis, SCIM-TS at 6 months after injury could be predicted based on only six variables, i.e., age at injury, three key muscles (C6 wrist extensors, C8 finger flexors, and L3 knee extensors), and two mobility assessments (WISCI and SCIM−item13) (Adjusted R-Squared: 0.83). These six independent variables were significant factors reflecting SCIM-TS at 6 months.

Conclusions In rehabilitation after traumatic spinal cord injuries, a simple and reliable prognostic model can help accurately predict the achievable activity of daily living competency to set a goal. In addition, if the procedure is simple, evaluation can be completed in a short period of time, and the physical burden on both treating staff and patients can be reduced.

Introduction

Traumatic spinal cord injuries (SCI) involve dislocation fractures of the spine and vertebral body fractures due to high energy external forces applied to the spine, such as in traffic accidents, falls, and sports. Or cervical SCI without major bone injury due to falls during walking or other similar causes [1]. Consequently, because the spinal cord parenchyma is damaged, neurogenic bladder, rectal disorders, central neuroparalysis such as sensory impairment and motor impairment permanently occur, resulting in drastic changes in the individual’s lifestyle [2].

Functional recovery after traumatic SCI is more efficiently facilitated by rehabilitation treatment. An important efficacy outcome of the treatment is how to regain the competency in activity of daily living (ADL) [3]. Functional recovery after traumatic SCI largely depends on neurological recovery of the injured spinal cord parenchyma. In

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addition, recoverable ADL skills are also dependent on personalized rehabilitation programs.

The forecasted ADL competency of a patient with traumatic SCI serves as an indicator of treatment goal for medical professionals and the patients themselves and can demonstrate the importance of rehabilitation if its accuracy is supported by scientific evidence. When examining functional outcomes in rehabilitation treatment, the Spinal Cord Independence Measure version III (SCIM) is one of the most important assessment tools for evaluating ADL of patients with SCI [4]. In recent years, studies on prognosis after traumatic SCI have been conducted from various aspects, such as surgical intervention starting in the hyperacute phase [5], drug therapy effects [6–8], and regaining walking ability [9, 10]. However, only a few reports have shown serial changes in functional recovery with a focus on ADL.

We hypothesized that the SCIM Total Score (SCIM-TS) at 6 months after injury may be accurately predicted using clinical factors collected at 1 month with a performance of multiple liner regression model as measured by R-Squared. This study aimed to develop a model for prediction of SCIM-TS in patients with traumatic SCI and identify factors affecting ADL at 6 months after injury. Given deficient dealing of studies with the prognosis of SCIM, this study plays an important role in improving the knowledge about recovery of not only physical functions but also ADL competency in general.

Methods

Setting

This study was conducted at the spinal injuries center at Fukuoka in Japan, a hospital specializing in spine and SCI (Located in western Japan, providing care from acute phase with or without surgery; social return of 700 cases of spinal surgery annually; treatment of approximately 80 patients with traumatic SCI annually). All the participants diagnosed with SCI at local emergency hospital were immediately brought to our spinal injuries center. On the same day, the participants underwent diagnostic imaging of the spine and surgery if required. Acute treatment was performed in the intensive care unit. Rehabilitation treatment was initiated on the first day after surgery in principle, or otherwise as early as possible, and continued until discharge.

Japan Single Center Study for Spinal Cord Injury Data Base (JSSCI-DB)

The JSSCI-DB was conducted at the spinal injuries center in 2005, and 1,064 cases were registered from July 2005 to October 2018. This database was updated in 2012 according to the 2011 revision of the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) protocol [11].

As an overview of the JSSCI-DB, we collected test data over time for 134 outcome measures, including neurological assessments (e.g., American Spinal Injury Association (ASIA) scoring system and Frankel grade), physical function assessments [e.g., Walking Index for Spinal Cord Injury version II (WISCI)[12], SCIM], and health-related QOL assessments (e.g., EQ-5D-5L). Examinations were performed at 13 time points during hospital stay in principle.

Exclusion criteria for the JSSCI-DB were as follows: people who did not consent to participation, those with head injuries or other neurological diseases (such as Parkinson's disease), and those with paresis causing ADL problems before injury. In addition, this study was conducted after obtaining approval from the Institutional Review Board of our hospital.

Participants

The data of participants used in this study were extracted from the data after the JSSCI-DB was updated (2012-). We retrospectively analyzed the data of 534 patients with traumatic SCI who were hospitalized in the spinal injuries center between January 2012 and October 2018. The registered data were prospectively and periodically collected according to the JSSCI-DB protocol.

The inclusion criteria of this study were those who were admitted at least from 1 month to 6 months after injury and were registered in the JSSCI-DB and underwent detailed neurological assessments as well as SCIM and WISCI evaluation according to the ISNCSCI protocol.

The exclusion criteria of this study were those who were rated as E on the ASIA impairment scale (AIS) by 4 weeks after injury because they are independent in ADL without any finding of neurological deficit; and those who could not be follow-up within 6 months after injury for various reasons, including hospital transfer and being discharged. The error ranges of examination points allowed in this study were ±3 days (4 weeks) and ±2 weeks (6 months). People who underwent the necessary assessments, but who did not do so within an acceptable time range were excluded.

As selection of participants, 70 patients with the AIS of E within 4 weeks after injury (injury received–3 weeks) were excluded from the 534 patients registered in the JSSCI-DB. Of the 464 patients (the AIS of A–D), 327 lost to follow-up within 6 months after injury were excluded. Finally, 137 patients who met the inclusion criteria were included in this study.

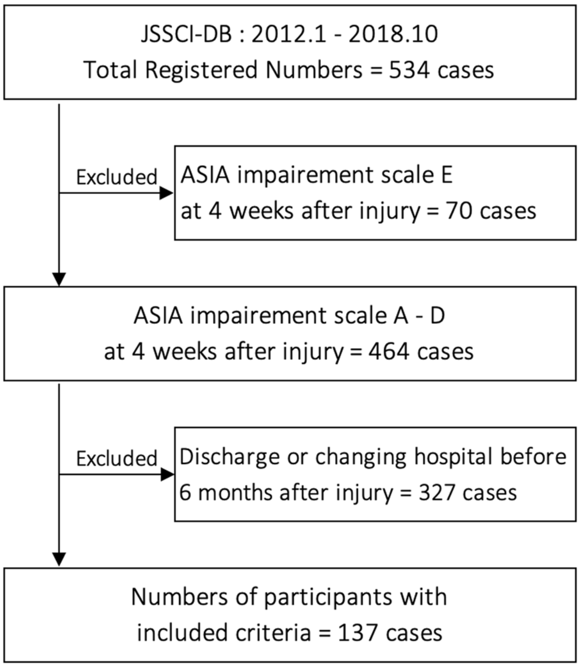

Fig. 1 Flow chart of participants inclusion criteria in this study. To select participants, 70 patients with the ASIA impairment scale (AIS) of E within 4 weeks after injury (injury received–3 weeks) were excluded from the 534 patients registered in the Japan Single Center Study for Spinal Cord Injury Database (JSSCI-DB). Of the 464 patients with the AIS of A–D at 4 weeks after injury, 327 lost to follow-up for reasons such as hospital transfer and being discharged within 6 months after injury were excluded. Finally, 137 participants who met the inclusion criteria were included in this study.

Outcome measurement

SCIM-TS results at 6 months after injury of participants who met the inclusion criteria of this study were used.

Candidate variables used for prediction model development

Candidate variables used were JSSCI-DB parameters used frequently by those involved in rehabilitation for SCI in daily practice and evaluation. Age at injury (1 variable) and results at 1 month after injury of ASIA motor key muscles (20 variables), ASIA key sensory points including light touch and pin prick (112 variables), SCIM-item scores (19 variables), and WISCI (1 variable) of participants who met the inclusion criteria of this study were used.

For ASIA motor key muscles, 10 key muscles based on the ASIA scoring system were used. The total upper extremity motor score and the total lower extremity motor score, which represents sum of motor scores, were not included in candidate variables. This was because the purpose of this study was to attempt to develop a simple, clinical, and highly accurate prediction model. The total upper and the total lower extremity motor score were also excluded from candidate variables because they always have a problem of multicollinearity.

Statistical analysis

We determined whether there were significant differences between 137 participants who met the inclusion criteria and 327 patients (excluding AIS: E) who were excluded. Student t-test and Mann–Whitney U-test were used for two-group comparisons of the basic medical information at 1 month after injury between participants in this study and those excluded.

A model to predict the dependent variable (SCIM−TS at 6 months after injury) from 153 candidate variables, which included the extracted data at 1 month after injury, was constructed using multiple linear regression analysis. Given the possible multicollinearity problem, correlations among 153 candidate variables were tested before designing the multiple regression equation.

Candidate variables were then listed using the regularized least squares regression method (lasso). Regarding the number of variables used as candidate variables, all combinations of up to 10 variables were selected as candidates based on the sample size and ease of use in actual clinical settings. Multiple regression analysis was performed using backward stepwise analysis on all combinations of up to 10 variables as predictors, and the predictive discrimination ability was determined.

Models were selected based on the Akaike Information Criterion (AIC). A model with a smaller AIC is considered more accurate in terms of model discrimination ability. Goodness of fit of the prediction model to data was evaluated with adjusted R-Squared values. The normality of residuals after model estimation was confirmed with a histogram, and the independence of residuals was confirmed with the Durbin–Watson test. The final model was chosen from among models with equivalent performance to that of the model with the smallest AIC, based on the number of variables used (the smaller the better) and the ease of use in a clinical setting.

In addition, the analysis data used did not have missing results at any time point used for subject selection, i.e., complete-case analysis. Outliers in analysis were identified based on residual histograms and Cook's distance in residual analysis. The identified outliers were checked retrospectively for the consistency on electronic medical records and were excluded as appropriate. In addition, when a variable had left and right values, Wilcoxon's signed rank-sum test was used for comparisons between the left and right groups, and positive and negative models were developed using the superior and inferior values, respectively, and tested.

The bootstrap method was used to test the validity and reproducibility of the final model selected. The bootstrap method is a resampling technique to extract a specified number of population samples from the data, assuming distribution of the population across the entire range of a variable being tested. The resampling procedure involves 1000 repeats of extraction from the participants, and the residual error after multiple regression analysis of each resample and 95% confidence interval of each independent variable were calculated for testing.

To facilitate the interpretation of specifications of the prediction model, the actual points and acquired percentages for SCIM Sub-score at 6 months after injury in participants in this study are shown in detail. A p value of <0.05 was considered statistically significant, and values were expressed as mean ± standard deviation. Statistical analyses were done with the MATLAB R2019a™ (The MathWorks Inc., Natick, MA, USA).

Results

Of the 534 participants registered at the JSSCI-DB of our center between January 2012 and October 2018, 137 participants meeting the inclusion criteria were included for analyses in this study. Figure 1 shows a flowchart detailing the inclusion criteria.

Table 1 shows the basic information of participants and excluded patients (age at injury, sex, and type of paralysis) who meet the selection criteria and details of AIS grade at after injury. The two-group comparisons of the basic medical information at 1 month after injury between the participants in this study and excluded patients showed that the AIS grade of the latter was significantly higher ($p < 0.01$). This result indicates that those who returned home within 6 months after injury or had similar outcomes were included, suggesting that the excluded data included cases with relatively mild paralysis and a high AIS grade.

After multiple regression analysis of 137 participants, the independent variables that were finally identified were age at injury, three key muscles (C6, wrist extensors; C8, finger flexors; and L3, knee extensors), and two mobility assessments (SCIM−item13 and WISCI) that were significantly associated with SCIM-TS estimates (adjusted R-Squared: 0.81, F-statistic vs. constant model: 96.5, $p < 0.001$). Measures used as independent and dependent variables are shown in Table 2. Names of variables used for prognosis prediction in this study and their measurement levels are shown in detail.

After the estimation of the prediction model, four outliers were identified using the residual histogram and Cook's distance in residual analysis. Electronic medical records associated with the outliers were retrospectively investigated, and three cases were identified in which SCIM-item 13 and WISCI assessments at 1 month after injury were inaccurate. In the remaining case, the individual concomitantly had severe dislocation of the right shoulder, and was unable to smoothly engage in the rehabilitation program early after injury. After excluding these four outliers, we reconstructed a prediction model with 133 individuals (adjusted R-Squared: 0.85, F-statistic vs. constant model: 127, $p < 0.001$).

Because variables with left and right values were selected in the prediction model, we performed Wilcoxon's signed-rank sum tests on the left and right groups of different ASIA motor key muscle levels, and found no significant differences. Therefore, we developed a positive model using values from the superior side and a negative model using values from the inferior side to improve convenience in a clinical setting. While the negative model did not show normality of residuals, the positive model provided high goodness of fit (adjusted R-Squared: 0.83, F-statistic vs. constant model: 111.5, $p < 0.001$) and was thus adopted as a prediction model in this study.

In the prognosis prediction equation, variables X1, X2, X3, X4, X5, and X6 denote C6 wrist extensors, C8 finger flexors, L3 knee extensors, SCIM-item13, WISCI, and age at injury, respectively. The positive model was as follows: Predicted $Y = 29.13 + 2.28 \times X1 + 4.17 \times X2 + 3.67 \times X3$

Table 1 The basic information of both participants and excluded patients.

Item	Participants	Excluded patients	p value
No. of Participants	137	327	
Age at injury	60.1 ± 16.0 (18–88)	60.6 ± 18.6 (18–92)	$p = 0.76^*$
Sex (male/female)	110/27	266/61	$p = 0.79$
Types of paralysis (tetraplegia/paraplegia)	114/23	261/66	$p = 0.40$
AIS grade at 4 weeks after injury			
A	49	104	$p < 0.01$
B	19	22	
C	44	65	
D	25	136	
AIS grade at 6 months after injury			
A	47	–	
B	10	–	
C	25	–	
D	55	–	

Age at injury is expressed as the mean ± standard deviation (ranges).

AIS ASIA impairment scale.

*The results according to Student t test; otherwise Mann–Whitney's U-test.

Table 2 Measurement levels of variables used in this study.

Name of variable	Measurement level	Staging	Substitution	Mean Median*	Standard deviation Interquartile distance*	Range	Interquartile range	Mode
SCIM-total score at 6 months after injury	Interval scale	0–100	–	44.57	26.12	0–96	–	10
C6 wrist extensors at 1 month after injury	Ordinal scale	6 stages	0,1,2,3,4,5	4*	2*	0–5	4	5
C8 finger flexors at 1 month after injury	Ordinal scale	6 stages	0,1,2,3,4,5	2*	2*	0–5	4	0
L3 knee extensors at 1 month after injury	Ordinal scale	6 stages	0,1,2,3,4,5	1*	2*	0–5	4	0
SCIM-item13 at 1 month after injury	Ordinal scale	9 stages	0,1,2,3,4,5,6,7,8	1*	2*	0–3	2	0
WISCI at 1 month after injury	Ordinal scale	21 stages	0,1,2,3,4,5,6,7,8,9,10,11,12, 13,14,15,16,17,18,19,20	0*	2*	0–17	0	0
Age at injury	Ratio scale	Continuous variable	–	60.1	16.0	18–88	–	63

SCIM the Spinal Cord Independence Measure version III, *WISCI* Walking Index for Spinal Cord Injury version II.

*indicates median and interquartile distance.

+ 6.75 × X4 + 1.48 × X5 + (−0.3) × X6. The partial regression coefficient, standard error, and other parameters of the prediction equation are listed in Table 3. Shown are estimates, standard error, tStat, and p values of coefficients estimated with the linear model for the intercept and X1-X6 of the positive model. For X1, X2, and X3, there are right and left variables, from which the superior value was used. Note that the partial regression coefficient for X6 (age at injury) is a negative value.

In Table 4, the points and percentages of the SCIM sub scores, i.e., "Self-care," "Respiration and Sphincter management," and "Mobility," are separately shown in increments of 20 points from the SCIM-TS measurement results for 133 participants in this study at 6 months after injury. Each score is shown as the mean ± standard deviation. In specifications of the prediction model, the details of SCIM-TS can be understood and the interpretation can be facilitated by referring to Table 4 after calculating the predicted points.

The result of the validity and reproducibility test of the final model using the bootstrap method showed a very small residual error of each resample after multiple regression analysis and the normal distribution. The 95% confidence interval obtained from the resampled data indicated an estimation precision level equivalent to that of our final model, demonstrating the validity and reproducibility of this prognosis prediction model. Table 3 shows the 95% confidence intervals of each regression coefficients estimated from the bootstrap resampling. Note that residual analyses were performed on all prediction models developed in this study, and models were found to be appropriate.

Discussion

We investigated the feasibility of predicting the ADL competency at 6 months after injury from physical findings at 1 month after injury using data extracted from a single-center, large-scale database of patients with traumatic SCI who underwent inpatient treatment at a spinal injuries center in Japan. The results indicated that a simple and clinical model could be developed to predict SCIM-TS at 6 months after injury based on six independent variables (age at injury, three key muscles, and two mobility assessments) presumed from among 153 candidate variables at 1 month after injury.

A simple evaluation procedure can shorten the length of time required for evaluation, ultimately reducing the physical burden on the treating physician as well as that on the person with traumatic SCI. AIS and neurological level of injury assessments in the ASIA scoring system requires to test 10 ASIA key muscles on the left and right, light touch and pin prick for 56 ASIA key sensory points on left and right, and functions associated with the S4-5 area (Deep

Table 3 Details of the estimated positive model.

Variable name		Estimate	SE	tStat	p value	95% CI[a]
Intercept		29.13	3.98	7.31	$p < 0.001$	21.91–37.10
X1	C6 Wrist extensors	2.28	0.75	3.04	$p < 0.01$	0.83–3.80
X2	C8 Finger flexors	4.17	0.68	6.11	$p < 0.001$	2.71–5.51
X3	L3 Knee extensors	3.67	0.56	6.62	$p < 0.001$	2.72–4.82
X4	SCIM item13	6.75	1.38	4.91	$p < 0.001$	4.09–9.52
X5	WISCI	1.48	0.32	4.71	$p < 0.001$	0.92–2.11
X6	Age at injury	−0.30	0.06	−4.79	$p < 0.001$	−0.41– −0.17

SCIM the Spinal Cord Independence Measure version III, *WISCI* Walking Index for Spinal Cord Injury version II, *CI* Confidence Interval.

[a]CIs were caluculated by the bootstrap resampling.

Table 4 The points and percentages of each SCIM sub scores.

SCIM total score at 6months after injury	Number of participants	Self care		Respiration and Sphincter management		Mobility	
score	n	score	%	score	%	score	%
0–20	27	0.5 ± 0.6	2.4	10.3 ± 4.0	25.6	1.4 ± 1.4	3.4
21–40	44	3.1 ± 2.2	15.5	20.2 ± 4.1	50.5	6.4 ± 2.6	16.0
41–60	21	8.2 ± 4.3	41.0	25.8 ± 4.6	64.5	14.6 ± 4.5	36.5
61–80	29	16.7 ± 2.9	83.4	32.1 ± 4.3	80.3	20.3 ± 4.1	50.8
81–100	12	18.7 ± 2.0	93.3	37.9 ± 2.3	94.8	34.7 ± 4.4	86.7

SCIM the Spinal Cord Independence Measure version III.

Each score is expressed as the mean ± standard deviation.

Anal Pressure/Voluntary Anal Contraction) [12]. It is indisputable that the ASIA scoring system is indispensable in assessing the severity of paralysis and the efficacy of treatment in detail and is the international standard evaluation method [13]. On the other hand, the prediction model developed in this study involves fewer test items and is simpler than the ASIA scoring system. Therefore, we extracted only uncombined variables in the ASIA scoring system for analysis rather than composite variables calculated secondarily.

Regarding age at injury, which is an independent variable, it has been reported that elder patients with SCI have less potential to translate neurological improvements into functional recovery than younger [14]. Even in our prediction model, the partial regression coefficient of age at injury was a negative value, and the finding that age at injury had a negative effect on the acquisition of ADL skills was similar to the results of the previous study.

The ASIA key muscles finally identified as independent variables were C6 wrist extensors, C8 finger flexors, and L3 knee extensors. The independent variables selected were statistically reliable. Our analysis probably derived variables important for ability to ADL general in patients with traumatic SCI.

In patients with traumatic SCI, C6 wrist extensors greatly affect eating and dressing actions, and are shown as upper limit among the key muscles to become independent in activity of daily living in an adjusted environment in several reports [15]. In addition, finger functions, including C8 finger flexors have been reported to contribute in the improvement of independency in overall ADL operations, such as self-care, sphincter management, and mobility [16]. The L3 knee extensors were reported to be an important independent variable for mobility evaluation in the ambulatory prognosis prediction model of the SCIM-item 12 (indoor mobility) by the EM-SCI Study group [9] as well as this study.

Both WISCI (evaluating 10-m walking ability) and SCIM-item 13 (moderate distance: 10–100 m) were identified as significant mobility assessments in this study. Therefore, the moving distance presumed to be an independent variable important for the functional outcome is 10 m, which is inferred to be a moving distance that is frequently encountered in daily life. The distance of 10 m is a frequently used reference value in the international metric system, and is used as a measurement for moving distances in the home [17]. In addition, parallel bars typical in a clinical setting are approximately 10-m long round trip. In other words, the ability to move 10 m at 1 month after traumatic SCI is a clinical and simple indicator for predicting the ADL competency at 6 months after injury.

Regarding the potential generalizability, the prediction model can be used for patients with AIS grade A–D at 1 month after injury. The model can also be used for all SCI patients with tetraplegia or paraplegia who are at least 18 years of age. This prediction model enables the prediction of the overall ability to ADL of patients with traumatic SCI at 6 months after injury based on clinical parameters at 1 month. Moreover, the selected independent variables are factors important for ADL at 6 months after injury, and appropriate assessment of and rehabilitation approach to these factors in clinical settings are expected to make a significant contribution to the ADL expansion at 6 months after injury.

There are some limitations in interpreting the results of this study. First, the participant's data in this study were collected from a single institution, and goodness of fit of the model was not tested using data from other institutions. Next, participants were included in this study only when data could be collected, i.e., from 1 month to 6 months after traumatic SCI. In other words, those who returned home or were transferred to a different hospital before six months of their injury had passed were excluded because they did not satisfy the inclusion criteria. Consequently, this study suggested that patients with relatively severe paralysis who required rehabilitation treatment to 6 months after injury fit this prediction model. Therefore, the prediction model developed in this study is applicable only to a specific period. To address these limitations, more data should be collected from multiple institutions according to the EMSCI-study group, which is a multi-center study.

Conclusions

A clinically simple and reliable prediction model with six independent variables was developed to predict SCIM-TS at 6 months after traumatic SCI. The six variables identified were age at injury, three key muscles (C6 wrist extensors, C8 finger flexors, and L3 knee extensors), and two mobility assessments, which were significant factors to predict SCIM-TS at 6 months after injury.

Data availability

Japan Single Center Study for Spinal Cord Injury Data Base was generated during and analyzed during the current study are not publicly available due viewpoint of personal information protection but are available from the corresponding author on reasonable request.

Author contributions YA was responsible for designing the review protocol, screening potentially eligible studies, analyzing data, interpreting results, creating'Summary of findings' tables, and writing the report. TH, RI and HK were responsible for designing the review protocol, screening potentially eligible studies, and interpreting results. SM and RK contributed to data extraction and provided feedback on the report. HS, YT, FT and TM contributed to arbitrating potentially eligible studies, and interpreting results.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics The study protocol was approved by the Institutional Review Board of the Spinal Injuries Center, and all participants provided written informed consent before participating in this study.

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