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学位論文

The Impact of Light Touch and Pin Prick on Functional Outcomes in Patients with Traumatic Spinal Cord Injury

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The Impact of Light Touch and Pin Prick on Functional Outcomes in Patients with Traumatic Spinal Cord Injury

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Running title: Impact of Sensory Scores on SCI Outcomes

Abstract

A spinal cord injury (SCI) can cause severe lifelong functional disability and profoundly affect an individual's daily life. We investigated the prediction of patients' post-SCI functional outcomes by evaluating sensory scores rather than motor scores, as the latter's association with functional outcomes is well established. We examined patients' responses to a light touch (LT) and pin prick (PP) at admission and the response data's usefulness as predictors of functional outcomes (i.e., ability to perform activities of daily living) at discharge. This exploratory observational study used data from the Japanese National Spinal Cord Injury Database (SCI-J). Data from 3,676 patients who met the inclusion criteria and were admitted for an SCI between 1997 and 2020 were analyzed. The motor score of the Functional Independence Measure (mFIM) at discharge was used as an index of functional outcome. A multiple regression analysis revealed that the mFIM was associated with both the LT response (β=0.07(0.01), $p<0.001$) and the PP response (β=0.07(0.01), $p<0.001$) at admission. The false discovery rate log-worth values for LT and PP were 6.6 and 8.5, respectively. Our findings demonstrate that LT and PP scores at admission can help predict patients' functional outcomes after an SCI, although the magnitude of their contributions is not high.

Keywords: functional independence measure, light touch, pin prick, spinal cord injury, Japanese National Spinal Cord Injury Database

Introduction

A spinal cord injury (SCI) can cause severe lifelong disability, profoundly affecting an individual's daily life due to complete or incomplete paraplegia or quadriplegia. The global incidence of SCIs is estimated to be 40–80 per million people annually, with the SCIs due mostly to traffic accidents, falls, and violence; these figures indicate that approx. 250,000–500,000 people are afflicted by an SCI each year [1]. The estimated incidence of SCI in Japan is 49 individuals per million people per year, which has a considerable impact on the country's society [2,3].

Early intervention is associated with improved outcomes in SCI [4], and early initiations of preventive measures and treatment can have beneficial effects on SCI patients. In addition, the patient's early and active mobilization is a key principle of rehabilitation [5]. The prediction of patients' functional outcomes is essential in rehabilitation planning for patients who have incurred an SCI, and such a prediction requires an accurate neurological examination conducted within 72 hours to 4 weeks after the injury [6,7]. The most commonly used tool to predict post-SCI outcomes is the International Standard for Neurological Classification of Spinal Cord Injury (ISNCSCI), which is used together with the American Spinal Injury Association (ASIA) Functional Impairment Scale (AIS) [8]. The ISNCSCI includes a motor component, i.e., the ASIA Motor Score (AMS) that is used to assess patients' motor function and a sensory score used to assess their sensory function. The AMS evaluates muscle strength based on the patient's achievement on the Muscle Manual Test (MMT), and the sensory score includes Light Touch (LT) and Pin Prick (PP) scores, which evaluate a patient's responses to touch and pain.

The association between patients' motor scores at admission and their functional outcomes, i.e., the ability to perform activities of daily living, has been well established [9–11]. However, few studies have evaluated sensory scores in this context, particularly for LT and PP. We conducted the present study to investigate the ability of SCI patients' responses to LT and PP at admission to predict functional outcomes at discharge.

Patients and Methods

Data sources

This was an exploratory observational study using a patient database and performed in accord with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement checklist. The database used in this study was the Japan Spinal Cord Injury Database (SCI-J) (<https://www.kibirihah.johas.go.jp/200_SCI_DB/top.html>; accessed July 23, 2023). The SCI-J was established in 1997; to date, 30 hospitals and two SCI centers have participated in the collection of data on traumatic SCI cases throughout Japan. The SCI-J database includes the following patient information: demographic information (age and sex), injury characteristics (mechanism and neurological level of injury), functional outcomes (level of daily activities), and discharge outcomes (discharge to the patient's home or a rehabilitation facility).

The study population was comprised of patients with SCI-J-registered cases who had been hospitalized between 1997 and 2020. A total of 5,774 cases were registered in the SCI-J database, among whom we selected 5,413 cases after excluding deaths and cases with data errors. Of these, 3,676 cases that met the following criteria were included in the analysis: age ≥18 years, ASIA AIS grade A–D on admission, and time from injury to admission ≤270 days; this period was used because the greatest part of neurological recovery generally occurs within 9 months of the injury, after which the rate of improvement declines rapidly [7,12]. Patients with missing data were excluded (Fig. 1).

Variables

The Light Touch score (LT) at admission and the Pin Prick score (PP) at admission were used as explanatory variables. LT and PP are methods of measuring sensory function in individuals with SCIs and are used in the ASIA AIS to determine the AIS grade and injury level [8]. These sensory tests are highly reliable and reproducible among evaluators [13]. The LT and PP measurements followed the ISNCSCI guidelines [14,15], which are the gold standard for the documentation of SCI levels and severity. Each patient's LT and PP responses were rated from 0 to 2 in each of the 28 dermatomes (from C2 to S4–5) on both sides of the body (0 = absent, 1 = altered [diminished or partial sensation, including hyperesthesia], 2 = normal or intact [similar to the cheek]); the higher the number, the more sensation was retained. The combined maximum score on both sides is 112.

The outcome variable was the Functional Independence Measure (FIM) at discharge as the functional outcome representing the ability to perform activities of daily living [16], for which the motor score of the FIM (mFIM) was used [11]. The mFIM is composed of four items: (*i*) self-care (eating, grooming, bathing, dressing–upper body changing, dressing–lower body changing, toileting), (*ii*) sphincter control (bladder management, urinary management, bowel management, defecation management), (*iii*) transfer, and (*iv*) locomotion (walk/wheelchair, stairs). Each item is scored on a scale of 1 to 7; the higher the score, the greater the degree of independence. The maximum possible score is 91.

The following covariates were used: the ASIA motor score (AMS) at admission, the AIS grade at admission, the FIM cognition score (cFIM) at admission, age (<65 or ≥65 years), sex, level of injury (cervical/below thoracic), injury mechanism (fall, fall from a height, traffic accident, sports, other), presence/absence of central cord injury, presence/absence of bone injuries to the spine, and comorbidities (diabetes, heart disease, lung disease, and renal disease). We used the Japanese version of the FIM (ver. 3.0), with culturally relevant modifications for some items [17–20]. Age was defined as the patient's age at admission, and we divided the patients into younger (<65) and older (≥65) age groups because the older the patient, the lower the mFIM has been during follow-up [21]. We classified the patients' level of injury into two groups: cervical (quadriplegic) and thoracic and below (paraplegic). Central cord injury is one of the clinical syndromes associated with SCI, and because it has a relatively good prognosis, we divided the patients into two groups according to the presence or absence of central cord injury [22,23].

Statistical analyses

Data related to continuous variables are expressed as means and standard deviations, whereas those in relation to categorical variables are expressed as proportions. To determine the relationships between explanatory and outcome variables, we used Student's t-test for the comparison of means for outcome variables that had two strata; a one-way analysis of variance (ANOVA) was used when the outcome variable had three or more strata. A multiple regression analysis was performed to determine whether the patients' LT and PP data were associated with their mFIM scores. We also created analysis of covariance (ANCOVA) models considering LT at admission and PP at admission, as follows.

- LT model: LT at admission + AMS at admission + cFIM at admission + sex + age category + injury mechanism + AIS at admission + level of injury + central cord injury + bone injury + diabetes + heart disease + lung disease + renal disease.
- PP model: PP at admission + AMS at admission + cFIM at admission + sex + age category + injury mechanism + AIS at admission + level of injury + central cord injury + bone injury + diabetes + heart disease + lung disease + renal disease.

We obtained the false discovery rate (FDR) log-worth to assess the order of the strength of the relationships between the covariates and the patients' mFIM scores at discharge. The statistical analysis was performed with JMP® Pro ver. 16.1.0 (SAS, Cary, NC, USA). The statistical tests were two-sided and performed with a significance level of 5%.

As this was an exploratory study using an existing database, no calculation of the required sample size was performed.

Ethical considerations

This study was approved by the Ethics Committee of Kagawa Rosai Hospital of the Japan Labor Health and Safety Organization (approval no. R4-30). Permission to use the SCI-J database was obtained from the National Spinal Cord Injury Database Management Steering Committee. All analytical procedures were performed in accord with the principles of the Declaration of Helsinki.

Results

The patients' characteristics

Of the 3,676 patients, 84% were male and 72% were <65 years of age. The most common mechanisms of injury were a fall from a height (34%), a traffic accident (32%), another type of fall (15%), and sports (6%). The AIS at admission was Grade A in 33% of the patients, Grade B in 11%, Grade C in 25%, and Grade D in 31%, with Grade A accounting for one-third of the patients. Regarding the level of disability, 71% of the injuries were at cervical level and 57% of the patients had bone injuries. Twenty-one percent of the patients had a central cord injury. In terms of comorbidities, 13% of the patients had diabetes, 7% had heart disease, 4% had lung disease, and 2% had renal disease. The mean mFIM scores at admission and discharge were 30.1 and 58.0, respectively, demonstrating that the patients' mFIM scores improved during their hospitalization. The mean LT and PP scores at admission were 66.4 and 62.4 points, respectively (Table 1).

Bivariate analysis

The patients' LT and PP responses at admission were significantly associated with sex ($p<0.0001$), age category ($p<0.0001$), injury mechanism ($p<0.0001$), AIS at admission ($p<0.0001$), level of injury ($p<0.0001$), central cord injury ($p<0.0001$), and bone injury ($p<0.0001$), with the patients with more severe injuries tending to have lower LT and PP scores (Table 1).

Multivariate analysis results

In the multivariate analysis, analytical models were created for LT and PP. In the LT model, LT on admission was associated with the mFIM score at discharge ($\beta=0.07$, standard error [SE]=0.01; $p<0.001$). Significant associations were also revealed for age, injury mechanism, AIS score on admission, level of injury, central cord injury, bone injury, diabetes, heart disease, AMS score on admission, and cFIM score on admission. In the PP model, PP on admission was associated with the mFIM score at discharge ($\beta=0.07$, SE=0.01; $p<0.001$), and significant associations were also observed for age, injury mechanism, AIS score on admission, level of injury, central cord injury, bone injury, diabetes, heart disease, AMS score on admission, and cFIM score on admission. The variance inflation factor (VIF) was low in both models (Table 2).

We identified the FDR log-worth of each factor in order to determine the magnitude of the factors' associations. In the LT model, the AMS score on admission was the largest contributor (236.5), followed by age (38.0), level of injury (24.4), and cFIM on admission (19.1). The LT response on admission was 6.6, and its contribution was not very high (Fig. 2). In the PP model, AMS on admission was also the largest contributor at 226.2, followed by age (38.7), level of injury (23.8), and cFIM on admission (19.5), whereas the PP response on admission did not contribute as much at 8.5 (Fig. 3).

Discussion

The results of our analyses of the cases of 3,676 patients with an SCI suggest that both the LT and PP scores (which are sensory assessments) at admission were significantly associated with the patients' mFIM scores at discharge. To our knowledge, most studies have focused on motor scores for predicting functional outcomes [9–11], with few analyses of sensory assessments. Saboe et al. showed a correlation between LT and PP data at admission and the FIM score at 2 years post-SCI, but this was based on an evaluation of the impact of post-discharge care and wheelchair use and not with FIM at discharge [24]. Kaminski et al. developed a predictive model for a spinal cord independence measure (SCIM) at 1-year post-SCI in which the LT score was included as a parameter [25]. Hicks et al. developed a predictive model of independent walking outcome after SCI in which the LT score at admission was used [26]. Thus, an association between a sensory evaluation (LT, PP) and functional prognosis in patients with SCI has been suggested, but few studies have analyzed SCI patients' functional outcomes at discharge, which is a novel focus of the present investigation.

We did not include interventions such as surgery as variables in the present models because we analyzed the impacts of LT and PP responses at admission on the mFIM at discharge. Early surgery has been reported to improve the outcomes of SCI patients in cases of spinal cord compression or instability [23, 27]. The mFIM score at discharge in our present patient population was 58.2 ± 0.58 among the patients who underwent surgery and 57.5 ± 0.82 among those without surgery, a nonsignificant difference ($p=0.484$).

We evaluated the patients' LT and PP sensory functions; a light touch is widely used to assess the extent of injury to the posterior columns of the spinal cord, whereas the use of a pin prick assesses the spinothalamic tract, with the light touch often having a greater value than a pin prick [28]. According to our present findings, the usefulness of the LT was greater than that of the PP, but the difference was small, and no apparent difference were identified between the LT and PP in terms of involvement in the patients' mFIM scores. In addition, although the AIS classification is commonly used as an index, in our study, the mFIM score was used as the functional outcome. The AIS is easy to understand with the five categories A–E, but it is difficult to evaluate the AIS result due to the presence of only five categories.

In a study that used the AIS classification as a functional outcome, the grade A patients showed little improvement; the grade B and C patients showed greater improvement, and the grade D patients showed little improvement, with a ceiling effect [29]. The use of the mFIM as an outcome measure in the present study was thus considered appropriate.

We set the patients' mFIM scores at discharge as this study's outcome variable, and the results of our analyses demonstrated that the patients' admission score on the AMS (which measures motor function) was a major contributor to their mFIM scores at discharge, as were other factors such as age, level of injury, central cord injury, cFIM at admission, LT at admission, and PP score. Since these factors are measured in patients who have experienced an SCI, they may be used to create prognostic nomograms of SCI. We also observed that the presence of diabetes and that of heart disease were associated with the mFIM at discharge. Diabetes is a particularly important health issue in Japan, where the number of individuals with diabetes continues to increase. Patients with stroke and diabetes have a lower mFIM at discharge [30], and a similar effect may be present in patients with SCI.

Study strengths and limitations

The strength of this study lies in the use of a major Japanese database with a sample size over 3,000. The participating facilities cover the entire country, and the data are considered representative of Japan; this increased the reliability of the results. This study also had the following limitations.

(1) The data collection was limited to the period from the patients' initial admission to their discharge,

with no information available after discharge; however, little improvement is expected at 9 months after SCIs [7,12], and this limitation is thus not expected to have significantly affected the results.

(2) Patient cases from 1997 to 2020 were analyzed, and changes in treatment and rehabilitation during that period were not taken into account. Although the ISNCSCI was revised during this period, no significant changes in the indicators used in this study existed, and the impact on the results is considered minimal.

(3) The variables collected were limited, with insufficient information on the patients' socioeconomic background and complications during hospitalization.

(4) A total of 880 cases were excluded due to incomplete data; however, this was <20% of the total number of patients who could have been included in the analysis and was not considered a selection bias.

In conclusion, among patients with a spinal cord injury, the Light Touch score and Pin Prick score at admission contributed to the prediction of the patients' functional outcome at discharge; however, the magnitude of these contributions was not large.

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Legends to Figures

Fig. 1. Flowchart of patient selection based on the study inclusion and exclusion criteria.

Fig. 2. The false discovery rate (FDR) log-worth of the parameters in the light touch (LT) model. FDR log-worth = -log10(FDR p-value). AMS: American Spinal Injury Association (ASIA) motor score; cFIM: Functional Independence Measure cognition score, AIS: ASIA Impairment Scale.

Fig. 3. The FDR log-worth of the parameters in the pin prick (PP) model. FDR log-worth = -log10(FDR p-value).

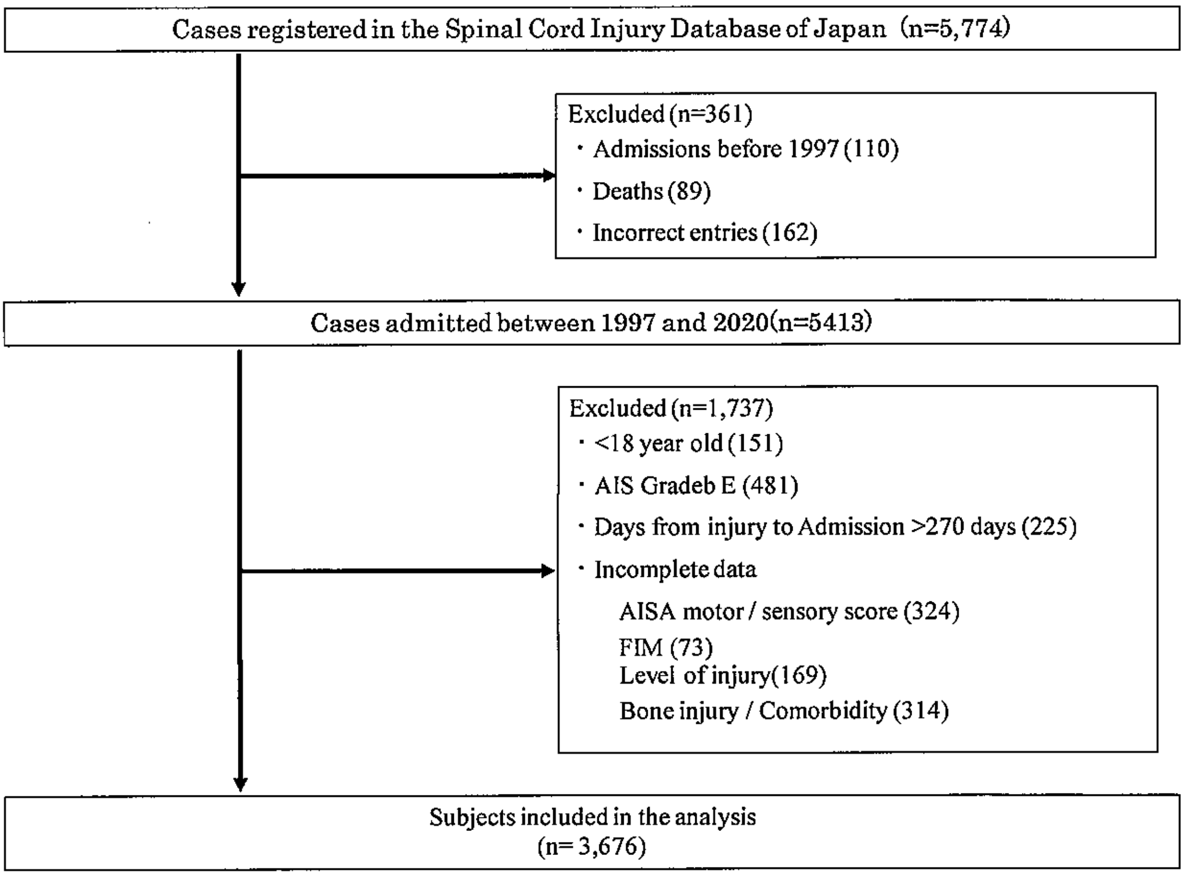

Figure 1 Flowchart of subject selection based on inclusion and exclusion criteria

Table 1 Characteristics of the subjects and light touch and pin prick scores at admission and mFIM at discharge

				Light touch score at admission		Pin prick score at admission		mFIM at discharge	
		n	%	mean (SD)	p	mean (SD)	p	mean (SD)	p
Total		3,676	100	66.4 (32.0)		62.4 (33.6)		58.0(28.7)	
Sex	Female	582	16	72.0 (32.2)	<.0001	68.3 (34.5)	<.0001	57.8 (1.2)	0.808
	Male	3,094	84	65.3 (31.8)		61.3 (33.3)		58.1 (0.5)	
Age	<65 years	2,658	72	65.2 (31.3)	<.0001	61.1 (32.9)	<.0001	62.0 (0.5)	<.0001
	≥65 years	1,018	28	69.6 (33.5)		65.9 (35.0)		47.7 (0.9)	
Mechanism of injury	Fall	568	15	74.2 (31.3)	<.0001	70.5 (33.7)	<.0001	55.4 (1.2)	<.0001
	Falls from height	1,232	34	65.8 (32.4)		61.7 (33.6)		54.8 (1.2)	
	Traffic accident	1,166	32	62.7 (32.0)		58.2 (33.4)		59.6 (0.8)	
	Sports	232	6	62.9 (29.9)		57.8 (31.9)		64.0 (1.9)	
	Others	478	13	69.4 (30.8)		67.1 (32.3)		62.7 (1.3)	
AIS at admision	A	1,205	33	41.7 (26.4)	<.0001	39.6 (26.7)	<.0001	46.2 (0.7)	<.0001
	B	403	11	62.4 (26.7)		52.3 (29.4)		46.0 (1.3)	
	C	911	25	73.2 (26.3)		67.3 (29.3)		53.8 (0.8)	
	D	1,157	31	88.2 (24.1)		85.9 (26.7)		77.8 (0.7)	
Level of injury	Cervical	2,626	71	62.7 (33.6)	<.0001	57.9 (35.1)	<.0001	51.6 (0.5)	<.0001
	Below thoracic	1,050	29	75.8 (25.0)		73.6 (26.1)		74.0 (0.8)	
Central cord injury	Yes	786	21	76.1(29.7)	<.0001	74.0(32.0)	<.0001	65.6(27.0)	<.0001
	No	2,890	79	63.8(32.0)		59.3(33.3)		55.9(28.8)	
Bone injury	Yes	2,103	57	62.9 (32.4)	<.0001	58.9 (33.6)	<.0001	58.8 (0.6)	0.058
	No	1,573	43	71.2 (30.8)		67.1 (32.9)		57.0 (0.7)	
			0						
Diabetes	Yes	475	13	69.0 (32.6)	0.062	64.1 (33.9)	0.300	50.6 (1.3)	<.0001
	No	3,201	87	66.0 (31.9)		62.2 (33.5)		59.1 (0.5)	
Heart diseases	Yes	243	7	69.6 (31.3)	0.148	65.3 (33.0)	0.205	49.9 (1.8)	<.0001
	No	3,433	93	66.2 (32.0)		62.2 (33.6)		58.6 (0.5)	
Lung diseases	Yes	133	4	62.3 (33.7)	0.156	57.8 (34.9)	0.101	48.3 (2.5)	<.0001
	No	3,543	96	66.6 (31.9)		62.6 (33.5)		58.4 (0.5)	
Renal diseases	Yes	89	2	68.9 (32.8)	0.397	66.5 (34.0)	0.202	53.7 (3.1)	0.154
	No	3,587	98	66.3 (31.9)		62.3 (33.5)		58.1 (0.5)	

p, p-value for Student t-test or oneway ANOVA.

SD, standard deviation; AIS, ASIA impairment scale; mFIM, motor scale of Functional Independence Measure; cFIM, cognition scale of Functional Independence Measure; AMS,ASIA motor score.

Table 2 Association of LT, PP and mFIM at discharge

variables		Multivariate analysis: LT Model			Multivariate analysis: PP Model		
		β (SE)	p	VIF	β (SE)	p	VIF
LT score at admission		0.07 (0.01)	<.0001	2.2			
PP score at admission					0.07 (0.01)	<.0001	2.2
AMS at admission		0.71 (0.02)	<.0001	3.9	0.70 (0.02)	<.0001	4.0
cFIM at admission		0.48 (0.05)	<.0001	1.1	0.49 (0.05)	<.0001	1.1
Sex	Female	-0.40 (0.38)	0.297	1.0	-0.42 (0.38)	0.273	1.0
Age	<65 years	4.56 (0.35)	<.0001	1.3	4.61 (0.35)	<.0001	1.3
Mechanism of injury	Fall	-2.12 (0.69)	0.002	1.8	-2.15 (0.69)	0.002	1.8
	Falls from height	-1.76 (0.50)	0.0004	1.4	-1.77 (0.50)	0.0004	1.4
	Traffic accident	1.00 (0.51)	0.050	1.4	1.04 (0.51)	0.042	1.4
	Sports	2.93 (0.93)	0.002	2.2	3.00 (0.93)	0.001	2.2
AIS at admision	A	1.30 (0.66)	0.048	3.7	1.05 (0.64)	0.101	3.5
	B	1.68 (0.73)	0.022	2.7	1.88 (0.73)	0.010	2.7
	C	-2.67 (0.52)	<.0001	2.0	-2.60 (0.51)	<.0001	2.0
Level of injury	Cervical	-4.32 (0.41)	<.0001	1.9	-4.26 (0.41)	<.0001	1.8
Central cord injury	Yes	2.23 (0.37)	<.0001	1.2	2.13 (0.37)	<.0001	1.2
Bone injury	Yes	0.84 (0.33)	0.011	1.4	0.85 (0.33)	0.010	1.4
Diabetes	Yes	-1.42 (0.43)	0.001	1.1	-1.39 (0.43)	0.001	1.1
Heart diseases	Yes	-1.23 (0.58)	0.033	1.1	-1.21 (0.58)	0.035	1.1
Lung diseases	Yes	-1.42 (0.75)	0.058	1.0	-1.40 (0.75)	0.062	1.0
Renal diseases	Yes	-0.31 (0.91)	0.735	1.1	-0.35 (0.91)	0.698	1.1
Adjusted R2		0.665			0.666		

ANCOVA for multivariate analysis.

SE, standard error; VIF, Variance Inflation Factor; ref, reference; AIS, ASIA impairment scale; mFIM, motor scale of Functional Independence Measure; cFIM, cognition scale of Functional Independence Measure; AMS,ASIA motor score. LT, Light Touch score; PP, Pin Prick score.

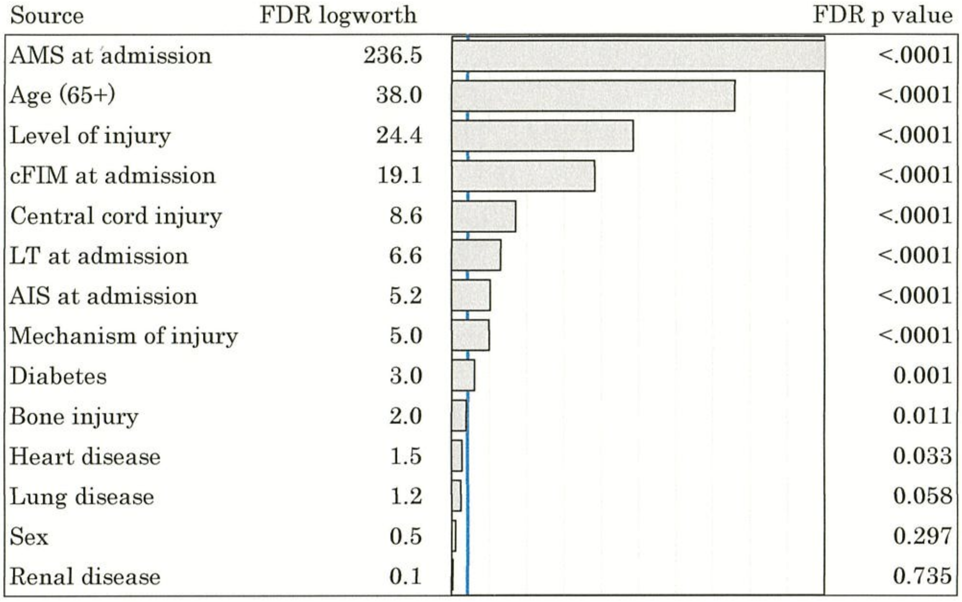

Figure 2 FDR Logworth of parameters in LT Model
FDR logworth =−log10(FDR p value)
AMS, American Spinal Injury Association (ASIA) motor score; cFIM, Functional Independence Measure cognition score; AIS, ASIA impairment scale.

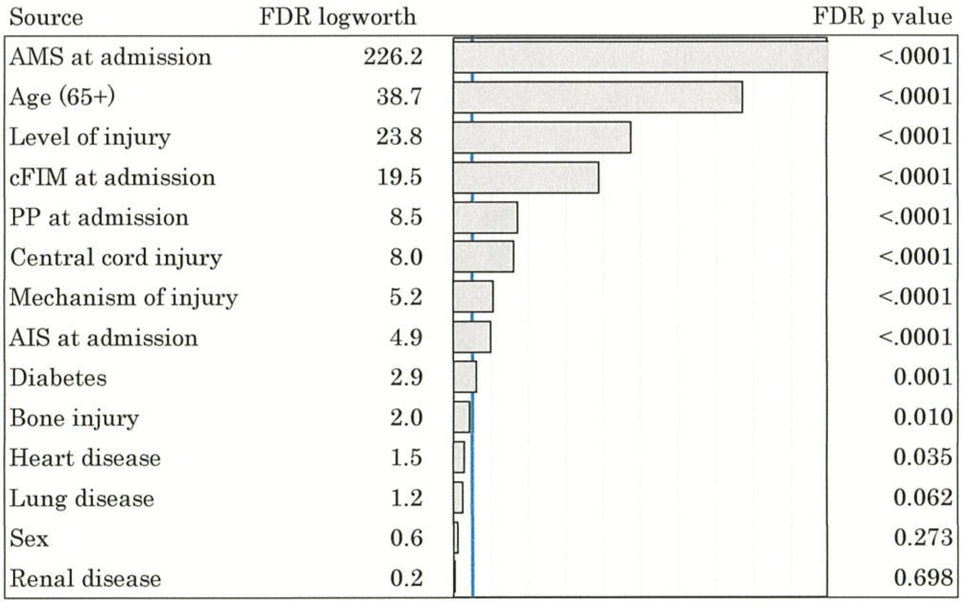

Figure 3 FDR Logworth of parameters in PP Model
FDR logworth =−log10(FDR p value)