# **ORIGINAL ARTICLE**

# Is determination between complete and incomplete traumatic spinal cord injury clinically relevant? Validation of the ASIA sacral sparing criteria in a prospective cohort of 432 patients

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Study design: Prospective multicenter longitudinal cohort study.

**Objective:** To validate the prognostic value of the acute phase sacral sparing measurements with regard to chronic phase-independent ambulation in patients with traumatic spinal cord injury (SCI). **Setting:** European Multicenter Study of Human Spinal Cord Injury (EM-SCI).

**Methods:** In 432 patients, acute phase (0–15 days) American Spinal Injury Association (ASIA)/ International Spinal Cord Society neurological standard scale (AIS) grades, ASIA sacral sparing measurements, which are S4–5 light touch (LT), S4–5 pin prick (PP), anal sensation and voluntary anal contraction; and chronic phase (6 or 12 months) indoor mobility Spinal Cord Independence Measure (SCIM) measurements were analyzed. Calculations of positive and negative predictive values (PPV/NPV) as well as univariate and multivariate logistic regressions were performed in all four sacral sparing criteria. The area under the receiver-operating characteristic curve (AUC) ratios of all regression equations was calculated.

**Results:** To achieve independent ambulation 1-year post injury, a normal S4–5 PP score showed the best PPV (96.5%, P<0.001, 95% confidence interval (95% CI): 87.9–99.6). Best NPV was reported in the S4–5 LT score (91.7%, P<0.001, 95% CI: 81.6–97.2). The use of the combination of only voluntary anal contraction and the S4–5 LT and PP sensory scores (AUC: 0.906, P<0.001, 95% CI: 0.871–0.941) showed significantly better (P<0.001, 95% CI: 0.038–0.128) discriminating results in prognosticating 1-year independent ambulation than with the use of currently used distinction between complete and incomplete SCI (AUC: 0.823, P<0.001, 95% CI: 0.781–0.864).

**Conclusions:** Out of the four sacral sparing criteria, the acute phase anal sensory score measurements do not contribute significantly to the prognosis of independent ambulation. The combination of the acute phase voluntary anal contraction and the S4–5 LT and PP scores, predicts significantly better chronic phase-independent ambulation outcomes than the currently used distinction between complete and incomplete SCI.

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# Introduction

All over the world, patients with spinal cord injury (SCI) are neurologically examined and classified according to the American Spinal Injury Association (ASIA) classification

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standards.<sup>1</sup> The ASIA classification has been revised several times since its primary introduction in 1982.<sup>1–3</sup> One of those revisions could be partially attributed to the issue of complete vs incomplete SCI. As formerly used criteria for 'neurological level of injury' and 'zone of partial preservation' seemed to be of limited prognostic value, Waters *et al.*<sup>4</sup> introduced the sacral sparing criteria in 1991.

The sacral sparing criteria consist of the following items: (1) S4–5 dermatome light touch (LT) sensation, (2) S4–5

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dermatome pin prick (PP) sensation, (3) anal sensation and (4) voluntary anal contraction (see Box 1).<sup>5</sup> Waters et al.<sup>4</sup> concluded that the sacral sparing criteria for complete injury. that is, 'no sensory and/or motor function at the sacral segments' and incomplete injury, that is, 'some preservation of sacral motor and/or sensory function', were simpler and more stable definitions of complete and incomplete SCI compared with the ASIA 1990 revision. The ASIA classification committee decided to revise these and other definitions in the ASIA 1992 standards revision.<sup>6</sup> After this major revision, minor redefinitions in the ASIA 1996 and 2000 standards resulted in the currently applied definition of complete injury: 'If voluntary anal contraction = No AND all S4–5 sensory scores = 0 AND any anal sensation = No, then injury is COMPLETE.' If otherwise, then the injury is regarded as incomplete.5

In both clinical practice and clinical SCI trials, one of the core aims of the ASIA standards is to classify the extent of neurological impairment.<sup>7,8</sup> Another important aspect of the standards is prognosticating chronic neurological recovery on the basis of the initial examination.<sup>3</sup> For this purpose, both neurological<sup>9,10</sup> and functional<sup>11,12</sup> outcome parameters have been applied in earlier prognostic studies.<sup>13</sup> Recovery of ambulatory function can be regarded as one of the most important functional outcome measures of interest. Recently, Ditunno et al.<sup>14</sup> showed that independent ambulation is a high priority for recovery among patients with SCI. Three instruments that address the level of dependence on ambulation have been validated in SCI patients, namely the FIM (functional independence measure),<sup>15</sup> the spinal cord independence measure (SCIM III<sup>16</sup>) and the WISCI-II (walking index for SCI).<sup>17</sup> Out of these three measures, the SCIM mobility items describe the gradual levels of dependence and the use of assistive devices in most detail. On the basis of nine scale items, the SCIM mobility items gradually range from total assistance to wheelchair use, to walking with aids, to walking without aids, and are therefore applicable to a broader range of SCI patients.<sup>18</sup>

With reference to the prediction of ambulatory recovery, a distinction between complete and incomplete SCI is commonly applied.<sup>19–21</sup> However, to date, the core elements of this distinction, the ASIA sacral sparing criteria, have not been validated with respect to chronic phase functional outcomes. It was our objective to validate the prognostic value of the acute phase sacral sparing measurements with regard to chronic phase-independent ambulation in SCI patients.

# Materials and methods

From January 2002 to October 2008, patients with traumatic SCI were enrolled in 16 centers within the framework of the 'European Multicenter Study on Human Spinal Cord Injury' (EM-SCI; http://www.emsci.org). Data on neurological and functional status were collected prospectively at the acute phase (that is, within the first 15 days post injury) and 1, 3, 6 and 12 months after injury. Patients with a non-traumatic spinal cord lesion, severe cognitive impairment, peripheral nerve lesion, (poly)neuropathy or craniocerebral injury were

#### Box 1

- The ASIA sacral sparing items:<sup>1,5</sup>
- 1. Voluntary anal contraction
- 2. S4–5 light touch sensory score
- 3. S4-5 pin prick sensory score
- 4. Anal sensation

Definition of the distinction between complete and incomplete SCI:<sup>5</sup>

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If
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• *voluntary anal contraction* = **absent** 

AND

• *all S4–5 sensory scores* = **absent** 

AND

• *any anal sensation* = **absent** 

then

- = injury is complete.
- Otherwise injury is incomplete.

not included in the EM-SCI database. Frequent causes of polyneuropathy were excluded by studying the history or by means of measuring the ulnar and tibial sensory nerve conduction velocity. The study protocols were approved by the local ethics committees, and the patients gave their informed consent before entering the study.

In this study, patients with a conus medullaris or cauda equina syndrome were excluded from the analysis. The cauda equina is defined as the bundle of spinal nerve roots, which extend below the apex of the conus medullaris. As the apex of the conus medullaris is normally located at the L1-L2 level, the L2 nerve roots are, by definition, the most cranial roots of the cauda equina. Subsequently, the spinal nerve roots originating from the epiconus (L4-S1 spinal cord segments) and conus medullaris (S2-S5 spinal cord segments) are also part of the cauda equina. As patients seldom suffer from clearly isolated conus medullaris or cauda equina injuries, differentiation between these syndromes is difficult and not always possible. In addition, the cauda equina has been associated with a favorable prognosis because of the potential peripheral nerve regeneration. Therefore, injuries below the neurological level L1, which potentially are conus medullaris and cauda equina syndromes, were grouped and excluded from the analysis.

### Physical examination

Neurological examinations were conducted according to the ASIA standards.<sup>1,5</sup> All patients with completely conducted acute phase examinations, namely ASIA motor scores, LT and PP sensory scores of all levels, including anal examination, were included for analysis. The acute phase ASIA/International Spinal Cord Society neurological standard scale (AIS)

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grades and the four sacral sparing measurements (see Box 1) were used for analysis. In each patient, only the best score of the levels, that is, right or left, were included for analysis. For instance, if a patient scored a S4–5 LT left 1 and right 2, then the best S4–5 LT score was regarded as 2. Clinical assessments were conducted by trained and certified neurological and rehabilitation physicians having at least 1 year of experience in examining SCI patients. ASIA scores were recorded in the electronic EM-SCI database and the quality and correctness of the data were monitored centrally. In complete patient records, AIS grades were computed automatically according to the ASIA standards.<sup>1</sup>

#### Functional outcome

Recovery of independent ambulation was defined as the primary functional outcome. The SCIM indoor mobility (<10 m) item was assessed and analyzed for this purpose. The SCIM items address the ability to accomplish activities of daily living. Besides self-care items, the SCIM also assesses the level of dependency in indoor and outdoor ambulation. The SCIM mobility items gradually range from total assistance to wheelchair use, to walking with aids, to walking without aids. The SCIM version III<sup>16</sup> indoor and outdoor mobility items showed excellent reliability and construct validity.<sup>16</sup>

As the difference between indoor and outdoor mobility scores particularly reflect the difference in daily performance rather than in ambulatory capacity, only the indoor mobility follow-up scores were used for analysis. In addition, to distinguish dependent from independent indoor walkers, the SCIM indoor scores were converted to dichotomous outcomes. Patients who required total assistance, partial assistance to operate a manual wheelchair, a manual wheelchair without assistance or supervision while walking were grouped and scored as 'unable to walk or dependent on assistance while walking'. Patients who were able to walk with or without assistive devices, but without supervision, were grouped and scored as 'able to walk independently'. Thus, a cutoff level of the SCIM indoor mobility score was applied; scores 0-3 were grouped and defined as 'unable to walk or dependent on assistance while walking' and scores 4-8 were grouped and defined as 'able to walk independently' (see Box 2).16

Within the EM-SCI consortium, the SCIM version II was replaced by version III in November 2007. As these versions are identical with respect to the graded scores of indoor and outdoor mobility items, the indoor mobility scores of SCIM versions II and III were grouped. In patients with absent 1-year follow-up measurements, 6-months follow-up measurements were used for analysis.

#### Statistics

Patients were divided into two groups, namely those who were able to ambulate independently after 1 year and those who were not. Comparisons between groups were made using  $\chi^2$ -tests. The positive predictive values (PPVs) and negative predictive values (NPVs) were calculated from contingency tables with 95% confidence intervals (95% CIs) calculated using the binominal exact method.

Box 2 Spinal cord independence measure (SCIM) item 12: Mobility Indoors.<sup>15,16</sup> 0. Requires total assistance 1. Needs electric wheelchair or partial assistance to operate manual wheelchair 2. Moves independently in manual wheelchair 3. Requires supervision while walking (with or without devices) 4. Walks with a walking frame or crutches (swing) 5. Walks with crutches or two canes (reciprocal walking) 6. Walks with one cane 7. Needs leg orthosis only 8. Walks without walking aids \*: The cutoff level of the SCIM indoor mobility score applied in this study to distinguish patients who are unable to walk or are dependent of assistance while walking from patients who are able to walk independently.

Univariate logistic regression equations were then computed for each sacral sparing item separately. To identify the strongest predictive rule for ambulation in chronic phase after traumatic SCI, a stepwise backward multiple logistic regression was performed. All four sacral sparing items were entered into the model. The area under the ROC (receiver-operating characteristic) curve (AUC) was used to assess the performance of the items separately and the model in terms of the accuracy of correct prediction.<sup>22</sup> The ROC curve is a plot of the truepositive rate (sensitivity) against the false-positive rate (1-specificity) of the model. The curve illustrates the ability of the model to discriminate between patients who ambulate independently after 1 year and those who do not. A test with no better discriminative ability than what would otherwise be obtained by pure chance will have an AUC of 0.5, represented graphically by the area under a 45° line. The accepted statistical rule of the thumb is that a test with an AUC of < 0.7 has a poor discriminative ability, an AUC between 0.7 and 0.8 provides acceptable discrimination and a test with an AUC above 0.8 is considered to have an excellent discriminative ability.<sup>23</sup> The AUC ratio of the regression analysis was then compared with the AUC ratio of the predictive rule using currently applied distinction between complete vs incomplete SCI.<sup>24</sup> All statistical analyses were considered statistically significant when  $\alpha < 0.05$ . All data analyses were performed using the SPSS software package version 15.0 (SPSS, Chicago, IL, USA).

## Results

Of the 1366 trauma patients within the EM-SCI database, 600 (44%) met all of the study criteria (see Figure 1). The mean patient age at the time of injury was 45 years (range:



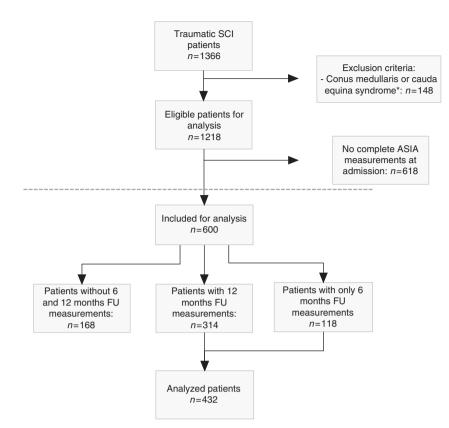


Figure 1 Flowchart of patients in the European Multicenter Study of Human Spinal Cord Injury (EM-SCI) database with subjects of patients eligible and included for analysis. Period of inclusion: January 2002–October 2008. \* Denotes neurological injury below level L1; FU, follow-up; SCI, spinal cord injury; ASIA, American Spinal Injury Association.

**Table 1** Chronic phase ability to ambulate independently in acute phase SCI patients (n = 432)

Type of acute phase SCI	Able to ambulate independently?		
	No	Yes	
Complete (AIS grade A)			
n	215	15	
%	93.5	6.5	
Incomplete (AIS grades B, C, D)			
n	72	130	
%	35.6	64.4	

Abbreviations: AIS, American Spinal Injury Association/International Spinal Cord Society neurological standard scale; SCI, spinal cord injury.

15–92 years); 79% of the patients were male, 58% had tetraplegia and 42% had paraplegia. One-year follow-up SCIM measurements were available in 314 (52%) of the included subjects. In the absence of 1-year follow-up measurements, 6-months follow-up measurements were used for analysis in 118 cases (20%). In total, 432 patients were analyzed (see Figure 1).

The mean time between injury and first ASIA assessment at the time of admission was 7.7 days  $\pm$  4.7 (range: <24 h to 15 days). A total of 114 patients (19%) were examined within 72 h post injury. At admission, 310 patients (52%) scored AIS grade A, 72 (12%) AIS grade B, 95 (16%) AIS grade C and 123 patients (20%) AIS grade D. Of all AIS grade A patients with available follow-up (n = 230), 215 of them (94%) were unable to walk or were dependent on assistance while walking. A total of 130 out of 202 incomplete SCI patients with available follow-up (64%) were able to walk independently (see Table 1).

PPVs and NPVs of the four sacral sparing items on the ability to walk independently are presented in Table 2. A normal S4–5 PP score showed the best PPV of 96.5% (P<0.001, 95% CI: 87.9–99.6). The S4–5 LT score showed the best NPV; the absence of LT sensation at the time of admission resulted in 226 of 244 patients (92.6%, P<0.001, 95% CI: 88.6–95.6) being unable to walk or being dependent on assistance while walking. The NPV of the absence of anal sensation and voluntary anal contraction on the functional outcome was 90.1 (P<0.001, 95% CI: 85.7–93.5) and 84.4% (P<0.001, 95% CI: 80.1–88.2) respectively.

The presence of anal sensation in the traumatic SCI patients resulted in a PPV of 66.7% (P<0.001, 95% CI: 59.3–73.5). In case the best score of the S4–5 LT and PP sensation was impaired (score 1) at admission, no significant differences existed between the PPV and NPV; 56.2 vs 43.8% (P=0.185) and 61.7 vs 38.3% (P=0.130), respectively.

Univariate logistic regression equations were computed for each sacral sparing item separately. With regard to the ability to walk independently, the predicted probability and effect

Sacral sparing items			Able to ambulate independently? <sup>a</sup>						
Item	Score	n	%	Yes (n)	PPV <sup>b</sup>	95% Cl <sup>b</sup>	No (n)	NPV <sup>b</sup>	95% Cl <sup>b</sup>
Voluntary anal contraction	0	327	75.7	51	15.6	11.8–20.0	276	84.4	80.1-88.2
,	1	105	24.3	94	89.5	82.0-94.7	11	10.5	5.4–18.0
Anal sensation	0	252	58.3	25	9.9	6.5–14.3	227	90.1	85.7–93.5
	1	180	41.7	120	66.7	59.3-73.5	60	33.3	26.5-40.7
S4–5 light touch score <sup>c</sup>	0	244	56.5	18	7.4	4.4–11.4	226	92.6	88.6–95.6
	1	128	29.6	72	56.2	47.2-65.0	56	43.8	35.0-52.8
	2	60	13.9	55	91.7	81.6–97.2	5	8.3	2.8–18.4
S4–5 pin prick score <sup>c</sup>	0	281	65.0	32	11.4	7.9–15.7	249	88.6	84.3-92.1
	1	94	21.8	58	61.7	51.1-71.5	36	38.3	28.5-48.9
	2	57	13.2	55	96.5	87.9–99.6	2	3.5	0.4-12.1

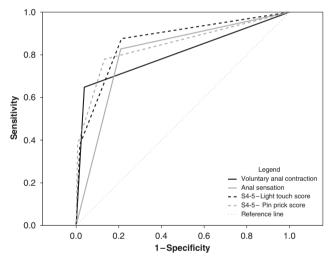
**Table 2** Positive and negative predicted values of the four acute phase sacral sparing items on the ability to ambulate independently in the chronic phase (n = 432)

Abbreviations: CI, confidence interval; NPV, negative predictive value; PPV, positive predictive value, SCIM, spinal cord independence measure.

<sup>a</sup>SCIM item 12 score  $\ge 4$  (yes) or  $\le 3$  (no). In case 1-year follow-up was not recorded, 6-months follow-up was used for analysis.

<sup>b</sup>Highest predictive values per sacral sparing item are italicized.

<sup>c</sup>Best score of each patient was used for analysis (that is, left or right).



**Figure 2** Area under the receiver-operating characteristic (ROC) for the four acute phase sacral sparing item measurements for discriminating between the ability to walk independently or not (n = 432).

sizes of each sacral sparing item are presented in Figure 2 and Table 3. All sacral sparing items did have an excellent ability (AUC above 0.8) for discriminating between the ability to walk independently or not (see Table 3).

Multiple logistic regression showed that only the voluntary anal contraction as well as S4–5 LT and PP sensory scores contribute significantly to the prognosis of independent ambulation. This model showed the best discriminating ability to predict between patients who were able to walk independently and those who were not (AUC: 0.906, P<0.001, 95% CI: 0.871–0.941, see Table 4 and Figure 3). Within this model, the anal sensory score (P=0.605) did not contribute significantly to the predictive probability of walking independently or not. The use of the predictive model without anal sensory score (AUC: 0.906) showed significantly better (P<0.001, 95% CI: 0.038–0.128) discriminating results than the use of the currently used **Table 3** Area under the ROC for the four acute phase sacral sparing item measurements for discriminating between the ability to walk independently or not (n = 432)

Sacral sparing item	Area	P-value <sup>a</sup>	95% Confidence interval	
			Lower bound	Upper bound
Voluntary anal contraction Anal sensation S4–5–Light touch score S4–5–Pin prick score	0.809 0.864	<0.001 <0.001 <0.001 <0.001	0.775 0.764 0.826 0.802	0.855 0.854 0.903 0.890

Abbreviation: ROC, receiver-operating characteristic.  $^{a}$ Null hypothesis: true area = 0.5.

**Table 4** Area under the ROC for the regression model and currently used ASIA 'complete' vs 'incomplete' SCI distinction for discriminating between the ability to walk independently or not (n = 432)

Model	Area	P-value <sup>a</sup>	95% Confidence interval	
			Lower bound	Upper bound
Regression model <sup>b</sup> Currently used model <sup>c</sup>		<0.001 <0.001	0.871 0.781	0.941 0.864

Abbreviations: ASIA, American Spinal Injury Association; ROC, receiveroperating characteristic; SCI, spinal cord injury.

<sup>a</sup>Null hypothesis: true area = 0.5.

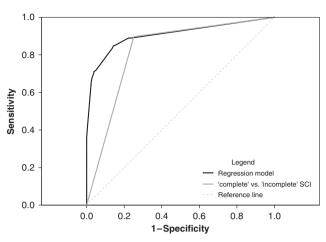
<sup>b</sup>Combination of acute phase voluntary anal contraction, S4–5 light touch and S4–5 pin prick score.

<sup>c</sup>ASIA 'complete' vs 'incomplete' SCI distinction.

distinction between complete and incomplete SCI (AUC: 0.823, P<0.001, 95% CI: 0.781–0.864, see Table 4 and Figure 3).

### Discussion

Determination of complete and incomplete SCI is commonly applied in prognosticating the functional recovery of patients.<sup>19–21</sup> Currently applied criteria of complete



**Figure 3** Area under the receiver-operating characteristic (ROC) for the regression model and currently used American Spinal Injury Association (ASIA) 'complete' vs 'incomplete' spinal cord injury (SCI) distinction for discriminating between the ability to walk independently or not (n = 432).

and incomplete SCI are based on the ASIA sacral sparing measurements. This is the first study we are aware of that examines the validity of the acute phase ASIA sacral sparing items in reference to chronic phase functional recovery. We found that, except for anal sensation, both minimum and maximum scores of the sacral sparing criteria provided high NPVs and PPVs with respect to chronic phase ambulation. The association between sacral PP preservation and improved ambulatory outcomes is consistent with that of earlier literature.<sup>12</sup>

Only 67% of patients with the presence of anal sensation in the acute phase after SCI, were able to walk independently at 6 or 12 months post injury. One possible explanation for this low PPV might be the controversy around the definition and technique of the anal sensation examination. Referring to Waters et al.,4 the most recent ASIA reference manual defines sacral sensation as follows: 'sensation at the anal mucocutaneous junction as well as deep anal sensation'.<sup>1</sup> Remarkably, Waters et al.4 did not mention deep anal sensation in the sacral sensation criteria: 'The presence of sacral sensation was determined by the presence of sensation in the perineum at the anal mucocutaneous junction, glans penis or clitoris.'4 Stauffer<sup>25</sup> did neither report on the prognostic value of deep anal sensation in one of the first descriptive studies with regard to sacral sparing. Other previous studies described the presence of visceral sensation in 'complete' SCI patients.<sup>26,27</sup> Hypothetically, deep anal sensation might also elicit visceral sensation and perhaps contribute to the low PPV of the anal sensation examination.

Regression modeling showed that only the combination of voluntary anal contraction and the S4–5 LT and PP sensation scores contribute significantly to the prognosis of ambulation. With respect to chronic phase ambulation, the distinction between acute phase complete and incomplete SCI resulted in a significantly lower AUC than the AUC of the regression model. In other words, omitting the anal

sensation score results in a better predictive model of independent ambulation than the currently applied combination of all four sacral sparing items. Therefore, we state that the currently applied distinction between complete and incomplete SCI is not the best indicator of ambulation recovery. This study stresses the importance of further research on this topic. In the end, these efforts may result in an optimal functional predictive algorithm in the acute setting of traumatic SCI care.

The eligibility criteria applied in this study resulted in a homogeneous traumatic SCI population of upper motor neuron lesions. Patients with a potential cauda equina and conus medullaris syndrome were excluded. The rationale behind these exclusion criteria is that injured peripheral axons regenerate, whereas central axons normally do not.<sup>28</sup> Although the effect of this evidence on functional recovery has not been investigated, we consider a clear central nervous system injury (SCI) to be different from a cauda equina injury. Another point of discussion remains, that is, the neurological cutoff level to exclude patients with potential cauda equina syndrome. The cutoff criterion was defined as injuries below neurological level L1 based on neuroanatomical considerations. To determine the validity of these pragmatic approaches, further investigation is warranted.

Within the EM-SCI database, validation of the sacral sparing was performed in a relatively large group of patients. Overall 52% of all patients completed 1-year follow-up. Six-months follow-up measurements were used in the case of the absence of 1-year follow-up measurements. A highly significant correlation was observed in patients with both 1-year and 6-month follow-up SCIM indoor mobility scores (n = 276, Spearman correlation: 0.887, P < 0.001). Therefore, replacement of the missing 1-year follow-up measurement by 6-month measurement is regarded as a valid approach.

As most of the EM-SCI centers are referral clinics, most ASIA measurements at admission have not been performed within 72 h post injury. In our study, acute phase measurements ranged from 0 to 15 days post injury. Although the timing of examination has been discussed frequently in the literature, no consensus exists regarding the difference between the prognostic value of immediate and subacute (>72 h) examinations.<sup>20,29,30</sup> Kirshblum *et al.*<sup>20</sup> concluded that the subacute examination may be more reliable for prognostic purposes because the immediate examination may be limited by associated injuries and level of alertness. On the other hand, once the period between injury, examination and treatment increases, more putative confounders might influence the analysis of the functional prognosis of patients.

One-year post injury independent ambulation was the outcome of interest in this study. The SCIM indoor mobility item was assessed and analyzed for this purpose. Other instruments addressing the level of dependence on ambulation have also been validated in SCI patients, the FIM<sup>15</sup> and WISCI-II.<sup>17</sup> The SCIM is currently recognized as the preferred global measure for assessment of clinical progress.<sup>14</sup> In this study, the gradual SCIM indoor mobility scores were converted to dichotomous outcomes for analytic purposes. Although this pragmatic approach resulted in a qualitative reduction of the data, we have been able to estimate the ability to walk independently indoors. Rather than capacity, the SCIM particularly addresses patients' level of dependence and performance achieved in daily activities in their current environment. Therefore, using the SCIM indoor mobility item as an outcome measure can be regarded as a valuable and clinical relevant outcome.

Some limitations of this study warrant consideration. Treatment regimens, including administration of methylprednisolone, blood pressure augmentation and urgent spinal cord decompression, are not standardized within the EM-SCI consortium. Furthermore, despite examinations by trained and certified neurological and rehabilitation physicians having at least 1-year of experience in examining SCI patients, inter-rater differences of neurological examinations remain inevitable because of the multicenter nature of this study. Nonetheless, recently, Savic et al.<sup>31</sup> showed a very strong inter-rater reliability of the clinical neurological examination performed according to the ASIA standards by experienced examiners. Another limitation of this study is the absence of details regarding spinal fractures and dislocations, co-morbidities, rehabilitation programs and walking aids within the EM-SCI database.

In conclusion, all sacral sparing items did have an excellent ability for discriminating between the ability to walk independently or not. Nonetheless, with respect to chronic-phase ambulation, a low PPV of the acute phase anal sensation examination was reported. Of the four sacral sparing criteria, the acute phase anal sensory score measurement does not contribute significantly to the prognosis of independent ambulation. The combination of the acute phase voluntary anal contraction and the S4–5 LT and PP scores, predicts significantly better chronic phase-independent ambulation outcomes than the currently used distinction between complete and incomplete SCI. This study stresses the importance of further investigation on functional predictive algorithms in the acute setting of traumatic SCI care.

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#### References

- 1 American Spinal Injury Association. International Standards for Neurological Classification of Spinal Cord Injury, revised 2003. American Spinal Injury Association: Chicago, IL, 2003.
- 2 American Spinal Injury Association. *Standards for Neurological Classification of Spinal Injured Patients*. American Spinal Injury Association: Chicago, IL, 1982.

- 3 Kirshblum SC, Memmo P, Kim N, Campagnolo D, Millis S. Comparison of the revised 2000 American Spinal Injury Association classification standards with the 1996 guidelines. *Am J Phys Med Rehabil* 2002; **81**: 502–505.
- 4 Waters RL, Adkins RH, Yakura JS. Definition of complete spinal cord injury. *Paraplegia* 1991; **29**: 573–581.
- 5 American Spinal Injury Association. *Standards for Neurological Classification of SCI Worksheet, Revised 2006,* Accessed: May 2008. Available from URL: http://www.asia-spinalinjury.org/publications/2006\_Classif\_worksheet.pdf.
- 6 American Spinal Injury Association/International Medical Society of Paraplegia (ASIA/IMSOP). International Standards for Neurological and Functional Classification of Spinal Cord Injury Patients (Revised). American Spinal Injury Association: Chicago, IL, 1992.
- 7 Fawcett JW, Curt A, Steeves JD, Coleman WP, Tuszynski MH, Lammertse D *et al*. Guidelines for the conduct of clinical trials for spinal cord injury as developed by the ICCP panel: spontaneous recovery after spinal cord injury and statistical power needed for therapeutic clinical trials. *Spinal Cord* 2007; **45**: 190–205.
- 8 Steeves JD, Lammertse D, Curt A, Fawcett JW, Tuszynski MH, Ditunno JF *et al.* Guidelines for the conduct of clinical trials for spinal cord injury (SCI) as developed by the ICCP panel: clinical trial outcome measures. *Spinal Cord* 2007; **45**: 206–221.
- 9 Waters RL, Adkins RH, Yakura JS, Sie I. Motor and sensory recovery following complete tetraplegia. *Arch Phys Med Rehabil* 1993; **74**: 242–247.
- 10 Marino RJ, Ditunno Jr JF, Donovan WH, Maynard Jr F. Neurologic recovery after traumatic spinal cord injury: data from the Model Spinal Cord Injury Systems. *Arch Phys Med Rehabil* 1999; **80**: 1391–1396.
- 11 Waters RL, Adkins R, Yakura J, Vigil D. Prediction of ambulatory performance based on motor scores derived from standards of the American Spinal Injury Association. *Arch Phys Med Rehabil* 1994; **75**: 756–760.
- 12 Oleson CV, Burns AS, Ditunno JF, Geisler FH, Coleman WP. Prognostic value of pinprick preservation in motor complete, sensory incomplete spinal cord injury. *Arch Phys Med Rehabil* 2005; **86**: 988–992.
- 13 Ditunno Jr JF, Burns AS, Marino RJ. Neurological and functional capacity outcome measures: essential to spinal cord injury clinical trials. *J Rehabil Res Dev* 2005; **42**(3 Suppl 1): 35–41.
- 14 Ditunno PL, Patrick M, Stineman M, Ditunno JF. Who wants to walk? Preferences for recovery after SCI: a longitudinal and cross-sectional study. *Spinal Cord* 2008; **46**: 500–506.
- 15 Granger CV, Hamilton BB, Keith RA, Zielesny M, Sherwin FS. Advances in functional assessment for medical rehabilitation. *Top Geriatr Rehabil* 1986; 1: 59–74.
- 16 Catz A, Itzkovich M, Tesio L, Biering-Sorensen F, Weeks C, Laramee MT *et al.* A multicenter international study on the Spinal Cord Independence Measure, version III: Rasch psychometric validation. *Spinal Cord* 2007; **45**: 275–291.
- 17 Dittuno PL, Dittuno Jr JF. Walking index for spinal cord injury (WISCI II): scale revision. *Spinal Cord* 2001; **39**: 654–656.
- 18 Lam T, Noonan VK, Eng JJ. A systematic review of functional ambulation outcome measures in spinal cord injury. *Spinal Cord* 2008; **46**: 246–254.
- 19 Kirshblum SC, Priebe MM, Ho CH, Scelza WM, Chiodo AE, Wuermser LA. Spinal cord injury medicine. 3. Rehabilitation phase after acute spinal cord injury. *Arch Phys Med Rehabil* 2007; 88(3 Suppl 1): S62–S70.
- 20 Kirshblum SC, O'Connor KC. Predicting neurologic recovery in traumatic cervical spinal cord injury. *Arch Phys Med Rehabil* 1998; 79: 1456–1466.
- 21 Burns AS, Ditunno JF. Establishing prognosis and maximizing functional outcomes after spinal cord injury: a review of current and future directions in rehabilitation management. *Spine* 2001; 26(24 Suppl): S137–S145.
- 22 Hanley JA, McNeil BJ. The meaning and use of the area under a receiver operating characteristic (ROC) curve. *Radiology* 1982; 143: 29–36.

- 23 Hosmer DW, Lemeshow S (eds). *Applied Logistic Regression*, 2nd edn. John Wiley & Sons: New York, USA, 2000, pp 47–69.
- 24 Hanley JA, McNeil BJ. A method of comparing the areas under receiver operating characteristic curves derived from the same cases. *Radiology* 1983; **148**: 839–843.
- 25 Stauffer ES. Diagnosis and prognosis of acute cervical spinal cord injury. *Clin Orthop Relat Res* 1975; **112**: 9–15.
- 26 Greving I, Tegenthoff M, Nedjat S, Orth G, Botel U, Meister V et al. Anorectal functions in patients with spinal cord injury. *Neurogastroenterol Motil* 1998; 10: 509–515.
- 27 Wietek BM, Baron CH, Erb M, Hinninghofen H, Badtke A, Kaps HP *et al.* Cortical processing of residual ano-rectal sensation in patients with spinal cord injury: an fMRI study. *Neurogastroenterol Motil* 2008; **20**: 488–497.
- 28 Neumann S, Woolf CJ. Regeneration of dorsal column fibers into and beyond the lesion site following adult spinal cord injury. *Neuron* 1999; **23**: 83–91.
- 29 Blaustein DM, Zafonte R, Thomas D, Herbison GJ, Ditunno JF. Predicting recovery of motor complete quadriplegic patients. 24 hour v 72 hour motor index scores. *Am J Phys Med Rehabil* 1993; 72: 306–311.
- 30 Brown PJ, Marino RJ, Herbison GJ, Ditunno Jr JF. The 72-h examination as a predictor of recovery in motor complete quadriplegia. *Arch Phys Med Rehabil* 1991; **72**: 546–548.
- 31 Savic G, Bergstrom EM, Frankel HL, Jamous MA, Jones PW. Interrater reliability of motor and sensory examinations performed according to American Spinal Injury Association standards. *Spinal Cord* 2007; **45**: 444–451.

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