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ORIGINAL ARTICLE

ASIA impairment scale conversion in traumatic SCI: is it related with the ability to walk? A descriptive comparison with functional ambulation outcome measures in 273 patients

JJ van Middendorp[1], AJF Hosman[1], MH Pouw[1], EM-SCI Study Group and H Van de Meent[2]

[1]*Spine Unit, Department of Orthopaedics, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands and* [2]*Department of Rehabilitation Medicine, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands*

Study design: Prospective multicenter longitudinal cohort study.
Objectives: To determine the relationship between improvements of the American Spinal Injury Association/International Spinal Cord Society (ASIA/ISCoS) neurological standard scale (AIS) outcome measure and improvements of functional ambulatory outcome measures in patients with traumatic spinal cord injury (SCI).
Setting: European multicenter study of human SCI (EM-SCI).
Methods: In 273 eligible patients with traumatic SCI, acute (0–15 days) and chronic phase (6 or 12 months) AIS grades, timed up and go (TUG) test and 10-m walk test (10MWT) outcome measurements were analyzed. Subanalysis of those patients who did have AIS conversion was performed to assess its relation with functional ambulatory outcomes.
Results: Studied population consisted of 161 acute phase AIS grade A patients; 37 grade B; 43 grade C and 32 acute phase AIS grade D patients. Forty-two patients (26%) converted from AIS grade A, 27 (73%) from grade B, 32 (75%) from grade C and five patients (16%) from AIS grade D. The frequencies of AIS conversions and functional ambulation recovery outcomes were significantly different ($P<0.001$) in patients with motor complete SCI. The ratio of patients with both recovery of ambulatory function and AIS conversion ($n=101$) differed significantly ($P<0.001$) between the acute phase AIS grade scores; AIS grade A (6/40 patients, 15%), B (9/27 patients, 33%), C (23/29 patients, 79%) and D (5/5 patients 100%).
Conclusions: The AIS conversion outcome measure is poorly related to the ability to walk in traumatic SCI patients. Therefore, the authors recommend the use of functional ambulation recovery outcome measures in prognosticating the recovery of walking capacity and performance of patients with SCI.
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Keywords: ASIA impairment scale; prediction; neurological outcome measure; functional ambulatory outcome measures; walking

Introduction

Recovery of walking is one of the most important aspects during rehabilitation in patients with spinal cord injury (SCI).[1] To quantify the recovery of walking, several functional ambulation outcome parameters have been introduced in past decades.[2] Nowadays, consensus exists concerning the importance of evaluation and validation of clinical trial outcome measures within the field of SCI research. In this field, three main classes of outcome measures have been postulated: (1) anatomical or neurological, (2) functional and (3) quality of life outcomes.[3]

The American Spinal Injury Association (ASIA)/International Spinal Cord Society (ISCoS) neurological standard scale (AIS) is currently regarded as the standard measure for neurologic outcomes.[3,4] Although the AIS is regularly used to classify the severity of initial SCI, the conversion rate of the AIS has also frequently been used as neurological outcome measure in clinical trials.[5–8]

Functional outcomes are regarded as the outcome measures of choice in clinical trials.[3] In a systematic review, Lam *et al*.[2] divided functional ambulation outcomes in two categories: timed and categorical measures of ambulation. Two of the timed measures are the timed up and go (TUG) test[9] and the 10-m walk test (10MWT),[10] both having an

Correspondence: JJ van Middendorp, Department of Orthopaedics, PO Box 9101, 6500 HB Nijmegen, The Netherlands.
E-mail: jvanmiddendorp@gmail.com
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excellent construct validity and reliability.[2,11] Two of the categorical measures are the functional independence measure[12] and the walking index for SCI (WISCI II/III),[13] with the latter showing an excellent construct validity and reliability.[2,14]

In clinical practice, the relation between neurological and functional outcome measures is a very interesting one. In several reports reviewing the prediction of neurologic recovery in traumatic SCI, the AIS conversion rates reported in studies have been extrapolated to and interpreted as the ability to walk in a pragmatic way.[15,16] To our knowledge, statistical relations between neurological (AIS) and ambulation outcome measures have not been reported in literature. It was our objective to determine the relationship between AIS conversion outcomes and improvements of functional ambulatory (TUG test and 10MWT) outcome measures in patients with SCI. We hypothesized that the AIS conversion rate is a relatively insensitive measure to determine the functional improvement compared with the functional ambulation outcome measures.

Methods

From January 2002 to December 2007, patients with traumatic SCI were enrolled within the framework of the European Multicenter Study on Human Spinal Cord Injury (EM-SCI; www.emsci.org). Data of neurological and functional status were prospectively collected at the acute phase (that is, within the first 15 days after the injury), and 1, 3, 6 and 12 months after the injury. Patients with a nontraumatic spinal cord lesion, severe cognitive impairment, peripheral nerve lesion, polyneuropathy or craniocerebral injury were not included in the EM-SCI database. In addition, patients with a central cord syndrome, conus medullaris or cauda equina injury were excluded from the analysis. Central cord syndrome was defined as an injury with a total lower extremity motor score of 10 or more points higher than the total upper extremity motor score. Conus medullaris syndrome or cauda equina injury was defined as a neurological level of injury at level T11 or below.

In patients with absent chronic phase (1-year) follow-up measurements, the 6-month follow-up measurement was used for analysis. The study protocols were approved by the local ethics committees and the subjects gave their written informed consent before entering the study protocol.

Physical examination

Neurologic examinations were conducted according to the ASIA standards.[4,17] All patients with completely conducted acute phase examinations, that is, ASIA motor score, ASIA pin prick score, ASIA light touch (sensory score of all levels and anal examination, were included for the analysis. Acute phase AIS grades of included patients were used for the analysis. On the basis of the ASIA sensory and motor scores, the level of injury and AIS grade were computed by a software program. This software program was used to exclude possible systematic errors in the AIS grading. Clinical assessments were conducted by certificated neurological and rehabilitation physicians having at least 1-year experience in examining patients with SCI.

Neurological and functional outcomes

The AIS improvement between the acute and chronic phases, the AIS conversion, was defined as primary neurological outcome. Two validated functional outcomes, both representing ambulatory capacity, were also assessed in each patient during follow-up. Ambulatory capacity was examined with TUG test[9] and 10MWT.[10] The TUG test measures the time it takes a patient to stand up from an armchair, walk 3 m, return to the chair and sit down.[9] Assessing short-duration walking in patients with SCI, the 10MWT measures the time it takes to walk 10 m.[10] The TUG test and 10MWT have both been validated in an SCI population.[11,18] However, in this study, the TUG test and 10MWT outcomes were not applied as continuous but as dichotomous (completed the test or not) variables. All patients who were able to complete either the TUG test or the 10MWT were defined as able to walk, regardless of the use of assistive devices or duration.

Statistics

Statistical analysis of data were performed with SPSS software package version 16.0. (SPSS, Chicago, IL, USA), and basically included a descriptive analysis of the investigated patient population. Incidence and frequency of both acute phase AIS grade and chronic phase neurological and ambulation outcomes were determined. Subanalysis, including χ^2 analysis, of those patients who had an AIS conversion was performed to assess the clinical improvements in terms of functional ambulatory outcomes.

Results

Among the 1170 trauma patients within the EM-SCI database, 377 (32%) met all of the study criteria (see Figure 1). The mean patient age at time of injury was 43 years (range: 15–92), 77% were men, 69% suffered tetraplegia and 31% of the patients suffered paraplegia. One-year follow-up of AIS measurements were available in 204 (54%) patients. In the absence of 1-year follow-up measurements, 6-month follow-up measurements were used for the analysis in 69 cases (18%). In total, 273 patients (72%) completed the follow-up (see Figure 1).

Mean time between injury and first ASIA assessment at admission was 7.3 days ± 4.8 (range: <24 h–15 days). Eighty-two patients (30%) were examined within 72 h after injury. Acute phase AIS grades of patients with complete follow-up are presented in the right column of Table 1. Most of these patients had a complete SCI ($n=161$, 59%). Chronic phase AIS grades of patients with complete follow-up are presented in the lower row of Table 1. Although 42 of the acute phase complete SCI patients (26%) improved to incomplete injury in the chronic phase, AIS grade A remained the major type of injury ($n=122$, 45%), see Table 1.

The majority of patients ($n=27$, 73%) with an acute phase AIS grade B injury improved neurologically to chronic phase

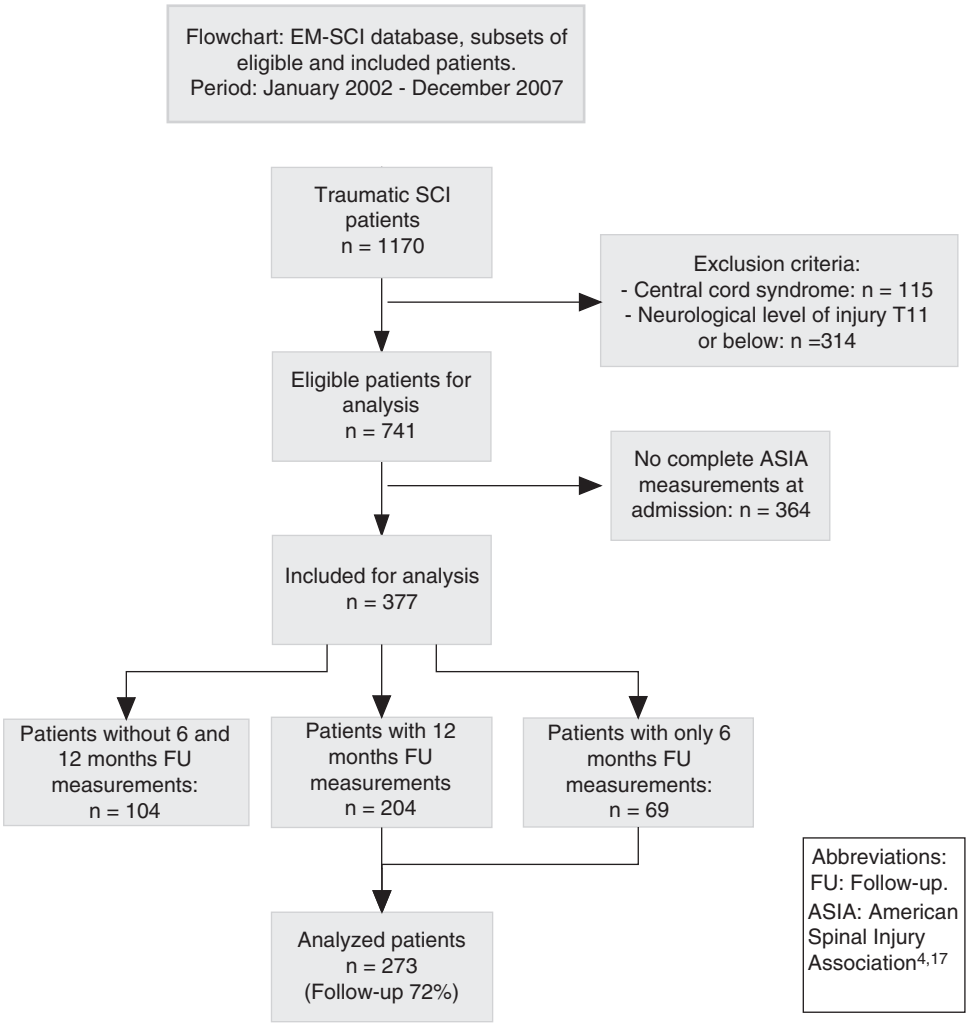

Figure 1 Flowchart of patients in the EM-SCI database with subsets of patients eligible and included for analysis.

Table 1 Acute phase AIS measures versus chronic phase AIS measures in included and eligible patients ($n=273$)

Acute phase AIS grade	*Chronic phase AIS grade*					
	A	*B*	*C*	*D*	*E*	*Total*
A	119	23	9	10	0	161
B	2	8	13	13	1	37
C	1	0	10	32	0	43
D	0	0	0	27	5	32
Total	122	31	32	82	6	273

Abbreviation: AIS, neurological standard scale.

AIS grade C ($n=13$, 35%), D ($n=13$, 35%) and E ($n=1$, 3%; (see Table 2). Thirty-two patients (75%) with acute phase AIS grade C improved to chronic phase AIS grade D. Although 27 patients (84%) with acute phase AIS grade D did not improved neurologically in the chronic phase, five patients (16%) recovered completely from the SCI (AIS grade E).

The joint distribution of the acute phase AIS grades and equal or improved chronic phase neurological and functional ambulatory outcomes are displayed in Table 2. Only 6 out of 42 patients (14%) who converted from complete SCI to incomplete injury were able to complete the chronic phase TUG test and/or 10MWT. All of these six patients scored chronic phase AIS grade D. Nine out of twenty-seven patients (33%) who improved neurologically from AIS grade B to AIS grade C ($n=1$), grade D ($n=7$) and grade E ($n=1$) completed the chronic phase ambulatory tests. In patients with motor complete SCI, the frequencies of AIS conversions and functional ambulation recovery outcomes were significantly different ($P<0.001$).

Twenty-three out of thirty-two patients (72%) who converted from AIS grade C to AIS grade D were able to walk 6 to 12 months after the injury. Ten acute phase AIS grade C patients did not improve neurologically according to the AIS grade scale. Yet, two patients within this group were able to walk and to complete the chronic phase TUG test. Within the acute phase AIS grade C patients, frequencies of AIS conversions and functional ambulation recovery outcomes were significantly different ($P<0.001$). All 32 patients with acute phase AIS grade D were able to walk and to complete

Table 2 Acute phase AIS measures versus chronic phase neurological (AIS) and functional ambulation (TUG test and 10MWT) outcome measures in included and eligible patients ($n=273$)

Acute phase measurements: AIS grade		Chronic phase measurements: AIS grade, TUG test and 10MWT												
		A	*B*	Number of patients completed		*C*	Number of patients completed		*D*	Number of patients completed		*E*	Number of patients completed	
				TUG test	*10MWT*		*TUG test*	*10MWT*		*TUG test*	*10MWT*		*TUG test*	*10MWT*
A	*n*	**119**	**23**[a]	0	0	**9**[a]	0	0	**10**[b]	5	5	**0**	0	0
	%	**74**	**14**	0	0	**6**	0	0	**6**	3	3	**0**	0	0
B	*n*	**2**	**8**	0	0	**13**	1	1	**13**	6	7	**1**	1	1
	%	**5**	**22**	0	0	**35**	3	3	**35**	16	19	**3**	3	3
C	*n*	**1**	—	—	—	**10**	2	1	**32**[c]	23	23	**0**	0	0
	%	**2**	—	—	—	**23**	5	2	**75**	53	53	**0**	0	0
D	*n*	—	—	—	—	—	—	—	**27**	27	27	**5**	5	5
	%								**84**	84	84	**16**	16	16

Abbreviations: AIS, neurological standard scale; TUG, timed up and go; 10MWT, 10-m walk test.
[a]One patient with missing chronic phase TUG test and 10MWT measurements.
[b]One patient with missing chronic phase TUG test measurement and one patient with missing chronic phase 10MWT outcome measurement.
[c]Three patients with missing chronic phase TUG test and 10MWT measurements.

Table 3 Recovery of ambulatory function in patients with AIS conversion of at least one grade and available chronic phase functional ambulation measurements ($n=101$)

Acute phase AIS grade	*Number of AIS conversion patients*	*Patients with both AIS conversion and recovery of ambulatory function (%)*
A	40	6 (*15*)
B	27	9 (*33*)
C	29	23 (*79*)
D	5	5 (100)

Abbreviation: AIS, neurological standard scale.

the chronic phase ambulatory tests. Five of these thirty-two AIS grade D patients (16%) improved neurologically to chronic phase AIS grade E.

Out of those 106 patients with chronic phase AIS grade improvement, 101 patients (95%) did also have available chronic phase functional ambulation measurements (see Table 3). In this subgroup, the ratio of patients with the recovery of ambulatory function and AIS conversion differed significantly ($P<0.001$) between the acute phase AIS grade scores; AIS grade A (6/40 patients, 15%), B (9/27 patients, 33%), C (23/29 patients, 79%) and D (5/5 patients, 100%).

Discussion

Until now, the relation between AIS conversion and functional ambulation recovery outcomes has not been investigated in patients with SCI. In this study, we found that the percentage of patients with both AIS conversion and recovery of ambulatory function during the first year after SCI differed significantly between the initial AIS grade groups ($P<0.001$). This confirms that the AIS conversion outcome measures reported in clinical trials should not be extrapolated to and interpreted as the ability to walk in a pragmatic way.

Acute phase AIS grade A patients improving to chronic phase grade B remain motor complete injured. Despite of their sensory recovery, they basically are not able to walk with or without assistive devices. In contrast, all patients with an initial AIS grade D without AIS conversion were able to walk 1 year after injury. This means that an AIS conversion is not necessarily associated with an ability to walk, and vice versa, a 1-year post-injury ability to walk does not always reflect an AIS conversion.

This study also shows remarkable differences in the ability to walk in patients improving to chronic phase AIS grade D. Approximately 50% of those patients having no acute phase motor function below the level of injury (AIS grade A or B) and who improved to chronic phase AIS grade D were able to walk after 1 year. Approximately 80% of acute phase AIS grade C patients who improved to grade D were able to walk. In addition, all of the acute phase AIS grade D patients without AIS conversion completed the functional ambulation tests. This pattern also confirms that AIS conversion to a specific grade is not necessarily associated with the ability to walk 1 year after injury.

Limitations of using the AIS as an outcome measure have been discussed in earlier studies. Instead of using the

standard AIS grades to assess neurological improvements, Jaeger *et al*.[19] proposed the use of the 'more than two motor or sensory points improvement' methodology. To date, however, this meticulous approach indicating the presence of functionally meaningful recovery has not been validated.

Recently, the clinical guidelines panel of the International Campaign for Cures of Spinal Cord Injury Paralysis (ICCP) articulated the importance of using more sensitive neurological outcome measures like the upper and lower extremity motor scores.[3,20] Comparing to the total ASIA motor score, Marino and Graves[21] showed that applying these separate neurological subscales for the degree of impairment, results in an improved prediction of functional abilities. Primary outcome of choice was the motor functional independence measure instrument score.[21] In another study, the SCI locomotor trial group concluded that the baseline lower extremity motor score was the best predictor of the WISCI score at 12 months.[22] However, with use of the same outcome measure, Wirz *et al*.[23] did not find a significant relation between lower extremity motor score improvement and recovery of ambulatory capacity. Neither improvements in impairment's severity (WISCI),[13] nor the dependency of assistance in daily care (functional independence measure),[12] but recovery of walking, is one of the prior preferences during rehabilitation in patients with SCI.[1] Therefore, we consider (the capability of finishing) timed functional ambulation outcome measurements to be more relevant in quantifying and predicting the recovery of ambulatory function. Nonetheless, applying the TUG test and 10MWT as dichotomous variables has not been validated and does not discriminate between household and community walkers. Further research is needed to categorize continuous ambulatory outcome measures in patients with traumatic SCI.[2]

Within the EM-SCI database, analysis was performed in a relatively large group of eligible patients. Seventy-two percent of patients completed the follow-up. The 6-month follow-up measurement was used in case of the absence of 1-year follow-up measurement. A highly significant correlation was observed in patients with both 1-year and 6-month follow-up AIS measurements ($n=174$, Spearman correlation$=0.907$, $P<0.001$). Therefore, replacement of missing 1-year follow-up measurement by 6-month measurement is regarded as a valid approach.

Patients with a central cord, conus medullaris or cauda equina syndrome were excluded from analysis because these syndromes have been associated with a favorable neurological improvement compared with classic tetra- and paraplegic recovery patterns.[24,25] As current central cord syndrome definitions lack specific quantified criteria, this injury was arbitrarily defined as an injury with a total lower extremity motor score of 10 or more points higher than the total upper extremity motor score. We also considered the recovery patterns of conus medullaris and cauda equina syndromes as potentially different from C1-T11 spinal cord injuries as these neurological syndromes are principally lesions of the peripheral nervous system. Although the exclusion of patients with a neurologic level of injury at level T11 or below resulted in a homogeneous SCI population, this approach was rather conservative and resulted in a relatively large proportion of tetraplegic patients.

Although timing of examination have been discussed frequently in literature, no consensus exists about the difference between the prognostic value of immediate and subacute (>72 h) examinations.[15,26,27] As most of the EM-SCI centers are referral clinics, most acute phase ASIA measurements have not been performed within 72 h after injury. In this study, 30 out of 82 patients (37%) with an examination within 72 h after injury improved at least one AIS grade during follow-up. This rate was not statistically different ($P=0.618$) compared with the conversion rate in patients with an assessment after 72 h and within 15 days after injury (76 out of 191 (40%)).

Some limitations warrant consideration. The number of recorded baseline demographic characteristics does not include all putative confounders. Treatment regimens, including administration of methylprednisolone, bloodpressure augmentation and urgent spinal cord decompression, are not standardized within the EM-SCI consortium. In addition, details concerning spinal fractures and dislocations, comorbidities, rehabilitation programs and walking aids have not been registered within the EM-SCI database. Furthermore, different AIS grade scales within the subgroup analysis resulted in relatively small patient numbers per group. Therefore, these results will require confirmation in another large sample population.

In conclusion, the AIS conversion outcome measure is poorly related to the ability to walk in patients with traumatic SCI. An AIS conversion is not necessarily associated with an ability to walk and vice versa (that is, a 1-year post-injury ability to walk does not always reflect an AIS conversion). Therefore, we recommend the use of investigated functional ambulation recovery outcomes in prognosticating the recovery of walking capacity and performance of patients with SCI.

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