

Determining Complete Functional Independence in Patients with a Traumatic Cervical Spinal Cord Injury: Proposal of a Two-Level Scale Based on the Spinal Cord Independence Measure

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Abstract

Objective: The SCIM scale is a valid measure of functional outcome for the spinal cord injury (SCI) population, but continuous scores are difficult to translate into functional independence (FI). The purpose of this study was to develop a new tool based on the third version of the SCIM questionnaire that would identify patients reaching complete-FI. In order to confirm that this new scale is relevant, we investigated whether it was associated with four factors often proposed as predictors of chronic functional outcome.

Design: A prospective cohort study including 109 patients with cervical traumatic SCI was performed. Based on a minimal score obtained on each item of the SCIM questionnaire, the cohort was dichotomized into complete FI (N=52) or non-complete FI (N=57). Baseline characteristics were compared between the two cohorts. A multivariate logistic regression analysis using age, trauma severity, and neurological characteristics of the SCI was performed.

Results: 52.3% of subjects reached complete-FI, sustaining less severe neurological deficits, a lower cervical SCI, and a less severe trauma with decreased associated injuries than non-complete FI patients ($p < 0.05$). Incomplete SCI (AIS grade B, C and D) and younger age were the main predictors of complete FI.

Conclusions: This new 2-level functional scale is easily applicable in a clinical setting, may be used retrospectively and provide meaningful information to patients and users on the functional recovery in the chronic phase following cervical SCI.

Keywords: Spinal cord injury; Functional independence; Tetraplegia; Function

Introduction

Determining the potential for functional recovery of a patient with a traumatic spinal cord injury (T-SCI) is crucial for the patients as they are coping with the distress caused by the trauma's debilitating consequences and its uncertain prognosis [1]. It is also of utmost importance for caregivers as it could help them develop an appropriate rehabilitation plan and successful community reintegration [2].

The SCIM is a valid and reliable disability measure, specific to patients with SCI, frequently used to evaluate the ability to perform activities of daily living (ADLs) independently, using a total from 0 to 100 [3-5]. Although Scivoletto et al. [6] reported that a 10-point increase is associated with substantial functional improvement, changes in the total SCIM score do not provide accurate information on the ability for SCI patients to perform all ADLs and tasks associated to mobility and transfers independently without assisted care, and therefore do not fully capture the concept of functional independence (FI) defined by the World Health Organization (WHO) as "the ability to perform activities with no or little help from others" [7].

Nevertheless, FI corresponds to a key issue for patients, healthcare professionals and researchers [8,9] and identifying patients with a potential for recovering complete FI is important in order to better orient their rehabilitation.

We have then developed an original and simple method to facilitate the prediction of FI based on the SCIM questionnaire. The purpose of this study was first, to describe this new tool, and to investigate its association with four recognized predictive factors of functional outcome (severity and level of the SCI, age and trauma severity) [10-13].

Methods

Patients

A prospective cohort of 109 adult patients with a cervical T-SCI consecutively admitted to a single Level I SCI-specialized trauma center between April 2010 and May 2015 (87 males and 22 females; 54.0 ± 17.3 years old) was used. Patients sustaining non-traumatic SCI, thoracic or lumbar levels of injuries were excluded. Patients were recruited at the time of admission if they sustained an acute T-SCI at the cervical level (C1 to C8) requiring surgical management, which

was performed in our institution. Patients had a follow-up visit with their treating surgeon at 6 month and/or 12 month post-trauma. The study was approved by the institutional review board and all patients were enrolled on a voluntary basis.

Data collection

Socio-demographic and clinical data were collected prospectively and updated on a daily basis during the acute care hospitalization. Collected data included age, gender and trauma severity as measured by the Injury Severity Score (ISS). The neurological level was used to discriminate between high cervical (C1-C4) and low cervical injuries (C5-C8). The severity of the SCI assessed upon arrival to the SCI-center prior to surgery, was reported using the American Spinal Injury Association (ASIA) impairment scale (AIS) grade.

Outcome assessment

The last version of the SCIM questionnaire (third version) was used to dichotomize functional status into complete FI and non-complete FI, which was used as the main outcome variable. The SCIM questionnaire is a disability scale that specifically addresses the ability of SCI patients to perform activities of daily living independently. It assesses three areas: self-care (evaluating feeding, grooming, bathing and dressing, for a sub-score of 0-20); respiration and sphincter management (for a sub-score of 0-40); and mobility and transfers (evaluating bed, indoor and outdoor mobility, for a sub-score of 0-40), so its total score varies from 0 to 100. Four questions assess self-care, three questions the sphincter management domain, one question assesses the respiratory management, four questions assess the mobility and transfer ability, and one question assesses the stair management (Table 1).

| Spinal Cord Independence Measure (SCIM)-version III Item | | Non-complete FI | Complete FI |
|--|---|-----------------|-------------|
| Self-care | Feeding (question 1) Bathing (questions 2A and 2B) Dressing (questions 3A and 3B) Grooming (question 4) | <2 | ≥ 2 |
| Respiration and sphincter management | Respiration (question 5) Sphincter management-Bowel (question 7) | <8 | ≥ 8 |
| | Sphincter management-Bladder (question 6) | <9 | ≥ 9 |
| | Use of toilet (question 8) | <4 | ≥ 4 |
| Mobility (bedroom and bathroom) | Mobility in bed and prevention of pressure sores (question 9) | <4 | ≥ 4 |
| | Transfers bed-wheelchair (question 10) Transfers wheelchair-toilet-tub (question 11) | <1 | ≥ 1 |
| | Mobility indoors (question 12) Mobility for moderate distance (question 13) Mobility outdoors (question 14) | <2 or=3 | =2 or ≥ 4 |
| Mobility (indoors and outdoors, on even surface) | Stair management (question 15) | <2 | ≥ 2 |
| | Transfers wheelchair-car (question 16) Transfers ground-wheelchair (question 17) | <1 | ≥ 1 |

Table 1: Cutoff values used to determine complete functional independence (FI) on each item of the SCIM scale based on the WHO definition of functional independence (WHO: World Health Organization [7]).

The SCIM questionnaire was administered during routine follow-up visits at 6 and/or 12 months post-injury. If the questionnaire was not available at one year, the 6-month SCIM score was used. Complete FI (as opposed to non-complete FI) was defined as reaching a specific cut-off value for all items of the SCIM questionnaire. Individuals present non-complete FI if they scored lower than the cut-off value for one or more items of the SCIM questionnaire. The cut-off value for each item corresponds to the sub score for which a patient is able to perform the task independently with or without assistive device or with little human assistance (Table 1). These cut-off values have been selected after consensus from three clinicians dealing with SCI (spinal surgeon, acute rehabilitation physician, and intensive functional rehabilitation physician).

Statistical analyses

Direct comparison analyses were first performed between individuals that have reached complete FI or non-complete FI. Continuous data were compared using Mann-Whitney U tests, while categorical data were compared using chi-square tests. Continuous data was reported as median and interquartile range (IQR), and categorical data were reported as proportions and percentages. Four candidate predictors were included in a multivariate logistic regression in order to determine if they were associated with complete FI in the chronic phase: 1) age; 2) pre-surgical AIS grade (AIS A, B, C, D); 3) neurological level (high cervical-C1 to C4 vs. low cervical-C5 to C8); 4) ISS. All statistical analyses were performed using the IBM SPSS Statistics 21 software (Chicago, IL), and results were considered statistically significant when $p < 0.05$.

Results

Of the 109 patients with a cervical T-SCI included in our analyses, the SCIM was available at 1 year post-injury for 70% of participants (n=76), and 6 months post-injury for 30% (n=33). Patients with a 1-year follow-up available were not different from patients with a 6-month assessment with respect to any clinical or socio-demographic characteristics.

Table 2 presents the socio-demographic and clinical characteristics of the 109 patients included in this study. There were 57 patients (52.3%) reaching complete-FI. The two groups were similar in terms of

age and gender. However, non-complete FI patients sustained more severe neurological deficits, with a proportion of 50% of individuals sustaining a complete SCI (AIS grade A) compared to 3.5% for the complete-FI group. The non-complete FI group also sustained a higher cervical SCI, with 71% of individuals had a C1-C4 SCI, compared to 35% for their counterparts. Finally, non-complete FI individuals experienced a more severe trauma with increased associated injuries (higher ISS) than complete FI patients ($p < 0.05$). The median SCIM total score was 44 for the non-complete FI groups, while it reached the highest score (100) in the complete FI group.

| | | Non-complete FI | Complete FI | p |
|--|---|------------------|--------------------|------------|
| N | | 52 | 57 | ----- |
| Age (median; IQR) | | 53.5 (35.8-65.0) | 57.0 (37.5-66.0) | ns |
| Gender (% male) | | 78.8 | 78.9 | ns |
| ISS (median; IQR) | | 22.5 (17.0-26.0) | 17.0 (16.0-19.0) | $<10^{-3}$ |
| Neurological level (% high cervical/C1-C4) | | 71.2 | 35.1 | $<10^{-3}$ |
| AIS grade (%) | A | 50.0 | 3.5 | $<10^{-3}$ |
| | B | 15.4 | 5.3 | |
| | C | 21.2 | 10.5 | |
| | D | 13.5 | 80.7 | |
| SCIM score (median; IQR) | | 44.0 (22.8-72.3) | 100.0 (96.5-100.0) | $<10^{-3}$ |

Table 2: Comparison of socio-demographic and acute care hospitalization clinical characteristics of patients with cervical SCI that reached and did not reach complete FI in the chronic phase post-SCI (n=109) (ns: non-significant; ISS: Injury Severity Score; AIS: ASIA Impairment Scale; SCIM: Spinal Cord Independence Measure; IQR: Interquartile Range).

The multivariate logistic regression analyses (Table 3) identified two variables significantly associated with the outcome (complete FI). Less severe AIS grades (B, C or D) and younger age significantly increased the odds of reaching complete FI within the first year following a traumatic cervical SCI, after controlling for other predictors. This model was statistically significant ($X^2=67.26$; $p < 10^{-3}$). Patients with

AIS B or C were approximately 10 to 15 times more likely to reach complete FI than patients with AIS A. The odds ratio of reaching complete FI for patients with an initial AIS D injury reached more than 260, when compared to AIS-A patients. Trauma severity based on the ISS and the neurological level of injury was not significantly associated with the occurrence of complete FI in the chronic phase after SCI.

| | Odds ratio | 95% CI | p |
|-----------|----------------|---------------|------------|
| AIS grade | 1 ^d | 1.24-89.64 | |
| A | 10.52 | 2.07-100.78 | 0.03 |
| B | 14.44 | 34.22-2040.93 | 0.01 |
| C | 264.30 | | $<10^{-3}$ |
| D | | | |
| Age | 0.95 | 0.92-0.99 | 0.01 |

Table 3: Factors associated with functional independence in the chronic phase post-SCI: results of multivariate logistic regression analysis (1^d: reference category; AIS grade: ASIA Impairment Scale; CI: Confidence Interval).

This regression model has allow us to appreciate that this new 2-level scale has identifies two of the main predictors of functional recovery recognized in the SCI literature [10-13].

Discussion

Predicting complete-FI following SCI is crucial for patients and care providers. Indeed, FI represents one of the main concerns of individuals sustaining a SCI, and easy identification of complete FI patients may significantly facilitate the rehabilitation plan and community reintegration [7,8]. This study proposes a new simplified

scale, identifying individuals who reach complete-FI following a cervical SCI. Not only it takes advantage of a reliable and validated outcome measure (the SCIM questionnaire) [3-5], but is also easy to interpret, meaningful for patients and care providers, and may be used retrospectively.

Our results showed that 52.3% of patients with a traumatic cervical SCI reached complete-FI six to twelve months after the SCI. Less than 10% of patients reaching complete FI had a motor-complete SCI (AIS A or B) which supports previous work suggesting that the severity of the SCI is the main and most consistent predictor of functional recovery [1,10,13]. Individuals with a motor-incomplete SCI generally present significant higher neurological and functional recovery in comparison with motor-complete SCI [14-16]. Accordingly, the logistic regression analyses showed that patients with incomplete SCI (AIS B, C or D) were more likely to reach complete FI (odds ratios between 10 and 264) as compared to patients with a complete AIS A cervical SCI.

Age was also inversely related to complete FI, as previously reported in the SCI literature [10,13,16]. Although it reached statistical significance in the logistic regression, its association with the FI scale was smaller than for the AIS grade. While age is not consistently related with neurological recovery, older individuals with SCI generally present more difficulty with regard to walking, bladder and bowel independence [17,18]. Older age by itself is also associated with higher risk of complications and mortality, as well as a higher number and severity of comorbidities, which may influence functional recovery [17,18]. Moreover, older adults may be affected by particular social issues, which may also impact community reintegration [17].

It is well known that functional recovery differs between cervical, thoracic and thoracolumbar injuries [19-21]. Unfortunately, there is no specific study in the literature that has specifically compared the FI between low and high cervical injuries. In this study, the neurological level of injury (low vs. high cervical) was not a significant predictor of the FI in the logistic regression analysis. This can be explained by the fact that the neurological recovery does not necessarily parallel the functional recovery [20,22].

The number and severity of associated injuries, as measured by the ISS was also not revealed as a predictive factor of complete FI in this study. A higher ISS score was previously suggested to be associated with reduced functional recovery in a general cohort of patients with SCI (including all levels of SCI) [11,23]. However, this association remain unclear in patients sustaining a cervical SCI. The most frequent associated traumatic injury in patients sustaining cervical SCI is traumatic brain injury, with an incidence of 40% [24]. Other traumatic injuries, such as concomitant chest, abdomen or extremity injury may occur in less than 6% of individuals with tetraplegia [23]. Although previous studies have suggested that individuals with paraplegia and co-occurring traumatic brain injury experienced reduced motor and functional outcome compared with individuals without traumatic brain injury, this was not found in tetraplegic subjects [24]. This might be explained by the fact that effects of concomitant traumatic brain injury on compensatory task, such as managing attendants and the use of adaptive equipment has not been evaluated yet. It is also possible that the presence of a high-energy mechanism of injury be more related to the functional outcome than the burden of associated injuries itself [11]. A future study should assess those issues.

Limitations

Most of the items of the SCIM can objectively distinguish between a patient who is able to perform the task independently with or without assistive device or with little assistance, and a patient who is dependent on human assistance. However, cut-off values had to be determined on a subjective manner for these items in order to extrapolate the associated impact on FI: 1) Sphincter management-bowel, 2) Sphincter management-bladder, 3) Mobility in bed and prevention of pressure sores, 4) Transfers bed-wheelchair, 5) Transfers wheelchair-toilet-tub. However for these five items, we have selected the cut-off values most likely associated with complete FI, as seen commonly in our clinical practice. Future studies will evaluate the accuracy of the cut-off values as related to their ability to properly determine the FI with regard to these five specific items.

Another limitation of this new FI scale relates to its strict criteria for classification, where a patient have to reach all the cut-off values for each item in order to be classified as complete-FI. In other words, failing to reach the cut-off value for only one item would classify a patient as non-complete FI. This classification method was establish according to the objective of this new scale; identify individuals completely FI. But also, this new scale may be particularly useful for identifying patients that will need additional resources to perform their daily living activities, as compared to complete FI patients. Future studies need to further investigate different subgroups of patients with non-complete FI, who can present variable degrees of dependence requiring specific needs.

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