

ORIGINAL ARTICLE

International Spinal Cord Injury Spinal Column Injury Basic Data Set

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Study design: Survey of expert opinion, feedback and final consensus.

Objectives: To describe the development of the International Spinal Cord Injury (SCI) Spinal Column Injury Basic Data Set.

Setting: International working group.

Methods: A committee of experts was established to select and define data elements. The data set was then disseminated to the appropriate committees and organizations for comment. All suggested revisions were considered and the final version was endorsed by both the International Spinal Cord Society (ISCoS) and the American Spinal Injury Association (ASIA).

Results: The data set consists of seven variables: (1) penetrating or blunt injury, (2) spinal column injury(ies), (3) single or multiple level spinal column injury(ies), (4) spinal column injury level number, (5) spinal column injury level, (6) disc and/or posterior ligamentous complex injury and (7) traumatic translation. All variables are coded using numbers or characters. For variables 1, 2, 3, 4, 6 and 7, response categories are assigned a numeric point score. Variable 5 assigns both characters and numbers to identify level(s) of spinal injured vertebra(e). When there are several distinct and separate levels of injury, then each one is described using variables 4 through 7.

Conclusion: The International SCI Spinal Column Injury Basic Data Set was developed to facilitate comparisons of spinal column injury data among studies, centres and countries. This data set is part of the National Institute of Neurological Disorders and Stroke Common Data Element project, and tools are now available to assist investigators in collecting this data in their SCI clinical studies. *Spinal Cord* (2012) **50**, 817–821; doi:10.1038/sc.2012.60; published online 5 June 2012

Keywords: spinal column injury; spine fracture; international data set; spinal cord injury; common data elements

INTRODUCTION

Traumatic spinal cord injury (SCI) frequently results in long-term disability that can prove life altering for both the injured person and their families.¹ These types of injuries have not only physical and psychological consequences but also have tremendous social costs associated with complex and prolonged treatment, rehabilitation and lost productivity.¹

Although a traumatic SCI can occur in the absence of a discernable injury to the spinal column,² there is an almost infinite number of injury patterns and locations along the spinal column. Great variability also exists in injury classifications and the nomenclature used to describe patient diagnoses. As the selection of an acute management strategy is often influenced by this nomenclature and classification methodology, it is not surprising that the variability extends to selection of treatment, to patient outcome.^{3,4} This variability further influences the education of healthcare personnel, scientific research and investigation, and overall health care costs.^{3,5,6} A widely accepted injury classification system would provide a common language and a more consistent approach to patient diagnosis and treatment; this would assist in the promotion of treatment strategies being tailored to specific

and identifiable injury patterns across centres (nationally and internationally) and within the treating physician community.⁷ The ideal system would provide a uniform method of injury description while simultaneously assisting the physician in their clinical decision making process.⁸

With specific regard to SCI, the complex anatomy of each vertebra and the multiple variations between vertebrae in different portions of the spine itself make simple classifications of fractures and fracture dislocations very challenging. Many classification schemes have been proposed over the last half century with several scoring systems developed for the assessment of spinal column injury and the resulting symptoms; however, none have yet been generally accepted for use as a tool to facilitate the standardization of the data collection process.^{7,9–14}

In 2002, a meeting of the International Spinal Cord Society (ISCoS) and the American Spinal Injury Association (ASIA) discussed a new initiative regarding the standardization of data collection and reporting for SCI studies.¹⁵ This initiative led to the development of the International SCI Core Data Set¹⁶ which includes a minimal amount of basic descriptive information that allows comparisons of underlying study populations in a manner such that the results are more

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accurately and easily compared across studies. The Core Data Set records the presence or absence of a spinal column injury, and the International SCI Spinal Column Injury Basic Data Set was developed to supplement the Core Data Set by collecting a minimal amount of data describing the spinal column injury(ies). The process used to develop the International SCI Spinal Column Injury Basic Data Set, a description of the data elements and examples of cases illustrating how the data is coded is described in this paper.

METHODS

The first draft of the International SCI Spinal Column Injury Basic Data Set was created by a working group consisting of members selected by the group's chair based on their expertise in the field of spinal column injury research, together with representatives of the Executive Committee of the International SCI Standards and Data Sets.¹⁵ The data set was developed with the intent that it could be used internationally, without great expense and without the need for sophisticated or advanced imaging capability. Although some classification systems require advanced interpretation of imaging studies such as MRI¹⁷ and the expert analysis of morphological patterns to discern a mechanism of injury,¹² we sought to avoid these complexities and make the data set valid in a wide spectrum of clinical environments and practical in the hands of a wide spectrum of clinicians. The development process for the International SCI Spinal Column Injury Basic Data Set involved the following steps:

- (1) The working group developed a first draft data set in 2008. This was further refined through an iterative process involving all the group members. A syllabus was developed to provide detailed definitions for each specific variable and response category.
- (2) The draft data set and its syllabus were reviewed by the members of the Executive Committee of the International SCI Standards and Data Sets project.
- (3) Comments from the Executive Committee members were discussed among the working group through e-mail and appropriate changes were made to the data set.
- (4) Relevant and interested International scientific professional organizations and societies as well as interested individuals reviewed the data set.
- (5) Comments from the International community were reviewed by the working group and changes were recommended and implemented.
- (6) Members of the ISCoS Scientific Committee and the ASIA Board reviewed the data set.
- (7) Comments from the committee/board members were discussed among the working group and further adjustments to the data set were made.

(8) The data set was finalized in May of 2011.

(9) Standard naming conventions for the variables of the data set were completed in collaboration with the National Institute of Neurological Diseases and Stroke (NINDS)/National Institutes of Health (NIH) Common Data Element (CDE) project.¹⁸

RESULTS

The International SCI Spinal Column Injury Basic Data Set is structured according to established protocol pertaining to International SCI Data Sets.^{18,19} The data set is included in the Supplementary Appendix and is currently available on the ISCoS website (www.iscos.org.uk).

There are seven variables in the data set and it is applicable to skeletally mature and skeletally immature individuals with a traumatic SCI. Collection of International SCI Spinal Column Injury Data Set may be conducted at any time following the injury. Each variable in the data set is described below. Three sample cases are provided to describe how the data set is coded (see Figures 1, 2 and 3).

Penetrating or blunt injury

This variable documents whether or not the injury is an 'open' or a penetrating injury, where the damage to the spinal column and neural elements has occurred secondary to a piercing object or projectile that has pierced the skin. The alternative is that of a blunt injury where the damage to the spinal column and neural elements occurs as a result of an impact transferred through the patient's tissues without penetrating the skin.

A numerical value is assigned with (0) representing blunt injury, (1) representing penetrating injury and (9) representing unknown.

Spinal column injury(ies)

This variable documents whether there is any disruption of the spinal column, including the bony vertebral elements and their supporting ligaments, capsules, discs, and other supporting soft tissues. A traumatic SCI may occur in the presence of no appreciable injury to the spinal column as in the case of cervical spondylosis and an acute traumatic central cord syndrome, which may occur with a spinal column that is completely intact from a structural point of view.

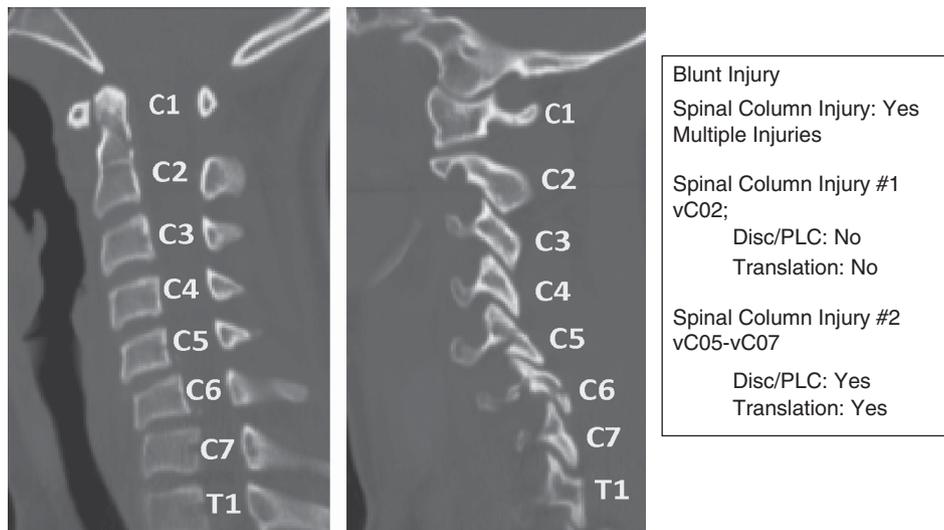


Figure 1 This patient has sustained multiple closed injuries of the cervical spine. In addition to the type II odontoid fracture, there are fractures of the C5 and C6 facet joints with a subluxation at both the C5-6 and C6-7 levels.

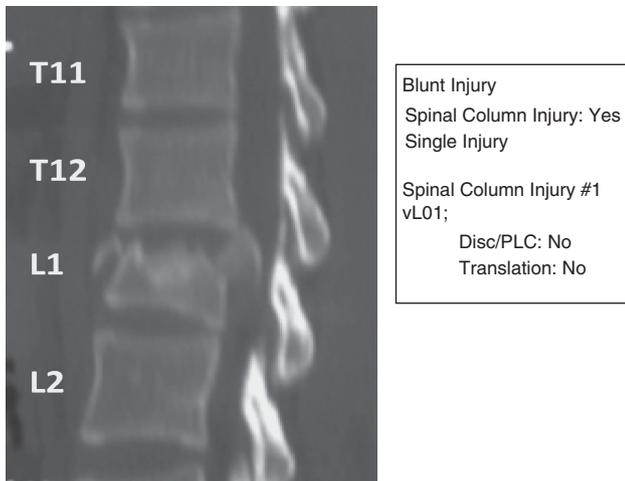


Figure 2 This patient has sustained an L1 burst fracture without ligament injury.

- at a single motion segment (for example, C5-6 bilateral facet dislocation) or
- over two or more adjacent and contiguous motion segments (for example, 'teardrop' fracture of C6 where the injury spans the C5-6 and the C6-C7 motion segments).

A multiple level injury consists of two or more single column injuries separated by at least one completely intact vertebral motion segment (for example, C5-6 facet dislocation and C2 Hangman's fracture).

A numerical value of (0) is assigned to indicate a single level spinal column injury. Where there are two or more discrete spinal column injuries (1) is assigned. The response (9) is selected when the presence or absence of a multiple level injury is not known.

Spinal column injury level number

This variable orders and assigns numbers to each level of injury in a patient's spinal column beginning with the most cephalic injury level and progressing to the most caudal level regardless of which level of spinal column injury is the most severe or significant injury or which injury may or may not contribute to the patient's neurological injury. If a patient were to suffer a Jefferson fracture of the atlas in association with a C6 burst fracture and an L1 compression injury, then each of these non-contiguous injuries would receive a numerical score beginning with 1 for the Jefferson fracture; 2 for the C6 burst fracture; and 3 for the L1 injury. In this clinical circumstance, variables 4 through 7 will be completed for each of the injury levels identified on imaging. The fourth variable will identify which injury in the cephalic to caudal order of injuries is represented in each group of variables.

A numerical value of (1) is assigned, if only one injury exists. A numerical value of (1) is also assigned to indicate the most cephalic of two or more spinal column injuries; (2), (3), (4) and others are assigned values for three or four discrete spinal column injuries with each number assigned in a progressive cephalic to caudal direction. The criteria for identifying separate injury levels remains as noted above; specifically each level of injury involves one or more adjacent vertebral levels and/or one or more adjacent and contiguous motion segments separated by at least one intact vertebral level separating the injuries above and below. The code (99) will be assigned when the order and assignment of spinal column injury levels is unknown

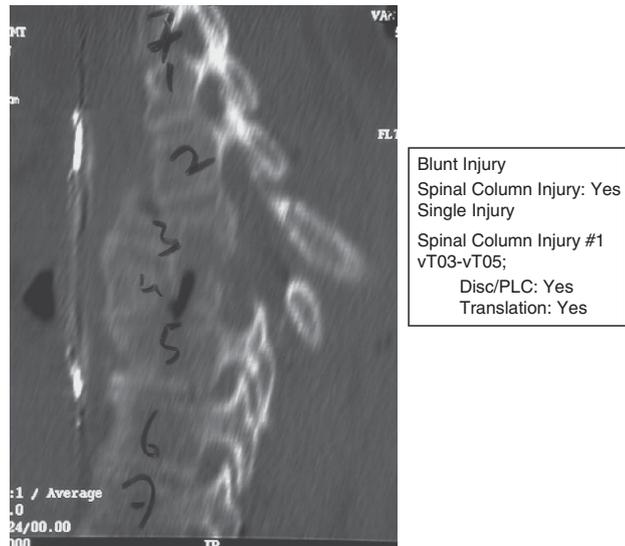


Figure 3 This patient sustained a complex thoracic fracture dislocation with an incomplete thoracic level SCI involving several vertebrae and segments from T3 to T5, multiple transverse process and spinous process fractures are observed on imaging.

Spinal column injury level

This variable is used to document each of the level(s) of spinal-injured vertebra(e). For a single vertebral level injury, such as a T5 burst fracture, the affected level alone is identified. For a single motion segment injury, such as a C5-6 facet fracture, both the cephalad and caudad of the two adjacent vertebrae are identified and separated by a dash (-).

The prefix 'v' references the fact that we are referring to a spinal column level (vertebral level) and helps distinguish the spinal column injury level from the neurological level. The cervical region is represented by vC00-vC07. The occiput is considered to be the most cephalic vertebral level and is designated by vC00. The thoracic region is represented by vT01-vT12. The lumbar region is represented by vL01-vL05. The sacrum is considered to be the most caudal vertebral level and is designated by vS01-vS05. When the specific spinal column level is not known, however, the spinal region (cervical, thoracic, lumbar and sacral) is known then the regions may be represented by vC99, vT99, vL99 and vS99 for cervical, thoracic, lumbar and sacral, respectively. When both the spinal column level and the region of the spine are not known, then these levels are documented as vX99. Where there are multiple spinal column

A numerical value is assigned to indicate (0) representing no disruption of the spinal column or (1) to represent any degree of disruption of the spinal column, disc and annulus, ligaments, and capsular structures, and (9) is assigned when the presence or absence of disruption of the spinal column is unknown.

Single or multiple level spinal column injury(ies)

This variable documents whether there is a single level spinal column injury or if there are multiple levels of spinal column injury separated by a motion segment of intact spinal column. A motion segment in the spinal column is defined as two adjacent vertebrae and their interconnecting discs and ligamentous structures. A single level injury may occur in several patterns. A single level injury may occur:

- at one vertebral level (for example, C6 burst fracture);

injuries, separate entries will be completed for each level of spinal column injury.

Disc and/or posterior ligamentous complex injury

This variable documents whether there is evidence of either a disc injury or a posterior ligamentous complex injury for each of the levels of the spinal injured vertebra(e). Disc injury is defined by a traumatic disruption of the annulus of the disc either through distraction, translation or rotation and it also includes traumatic disc protrusion causing a SCI. Acute injury to the posterior ligamentous complex is diagnosed radiographically and is identified by the presence of acute disruption or injury to the posterior ligamentous complex at any spinal column level from the occiput to the sacrum. Radiographic separation or widening of the inter-spinous distance, spondylolisthesis, displaced fracture or dislocation of the facet(s) in the presence of an acute kyphotic deformity is diagnostic of posterior ligament injury. Traumatic injury to the disc and annulus may occur in association with posterior element distraction, spondylolisthesis or dislocation and will be recorded as a concomitant disc and posterior ligamentous complex injury. In the case of multiple spinal column injuries, separate entries will be completed for each level of spinal column injury.

A numerical value of (0) indicates no to disc and posterior ligamentous complex injury; (1) indicates yes to either a disc or posterior ligamentous injury or a combination of both disc and posterior injury. When the status of the integrity of the disc and posterior ligamentous complex is unknown, a numerical value of (9) is assigned and indicates unknown.

Traumatic translation

This variable documents whether or not there is any traumatic translation (sagittal and/or coronal plane malalignment of adjacent vertebra) as evidenced on lateral and/or anterior–posterior radiographs, respectively. Translation is defined as sagittal or coronal plane malalignment of 3.5 mm or more of one cervical vertebra in relation to an adjacent vertebra²⁰ or movement of 2.5 mm or more of one thoracic²⁰ or lumbar vertebra on top of the adjacent vertebra for each of the spinal column injury level(s). Although the quoted reference was used to define the values for translation for the cervical and thoracic spine, the values for the lumbar spine as quoted in the same reference were changed based on the clinical expertise of the working group and also supported by the International review process.

A numerical value of (0) indicates that there is no evidence of traumatic translation; (1) indicates yes to traumatic translation. When the presence or absence of translation is not known, then a numerical value of (9) is applied. Malalignment secondary to a degenerative process, such as degenerative or isthmic spondylolisthesis, are not considered traumatic and should be recorded with the value (0). In the case of multiple spinal column injuries, separate entries will be completed for each level of spinal column injury.

DISCUSSION

This paper describes the development of an International SCI Spinal Column Injury Basic Data Set that will facilitate comparisons of spinal column injury data among studies, centres and countries. In an effort to keep this data set as useful and as easy to implement as possible, the working group kept the number of variables as brief as possible. The group achieved consensus regarding the seven items that are thought to include the most relevant components of a spinal column injury assessment.

It is recommended that the International SCI Spinal Column Injury Basic Data Set be used primarily in conjunction with the

background information attained from the International SCI Core Data Set.¹⁶ Included in the SCI Core Data Set is information such as date of birth, date of injury, date of admission, date of discharge, number of days in hospital, injury etiology, associated injury, spinal surgery and place of discharge. Baseline and discharge neurological data (sensory and motor level, and ASIA Impairment Scale) are also included. These variables are necessary to formulate an accurate patient profile and will assist in any research analyses, complementing the other spinal column injury specific data. For clinical and research purposes, the International SCI Spinal Column Injury Basic Data Set may benefit from the use of additional existing classifications that can provide information on the description and management of specific types of spinal column injuries.^{7,10,13}

Data should be collected in a consistent manner; use of a standardized format (data set) is necessary for collecting data quickly and accurately, and is essential when combining and comparing data from multiple sites is required to facilitate patient care excellence or for research purposes. For the aforementioned reasons, variables and response categories have been carefully chosen and specifically defined in an effort to promote the collaborative collection and reporting of comparable minimal data.

Administration of the International SCI Spinal Column Injury Basic Data Set to those individuals, whose primary language is not English, will require careful translation of the components. The working group recommends that a careful translation process be followed, adhering to the guidelines specifically recommended for use in translating the International SCI Data Sets as put forth by Biering-Sorensen *et al.*¹⁹

Lastly, although the International SCI Spinal Column Injury Basic Data Set was peer-reviewed by experts within the International community, it is expected that this data set will require periodic evaluation, revision and updating. Although this classification may change over time and as more knowledge is acquired, this simple and easily applied classification system will likely retain its utility for a number of years.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

Dr Peter Wing, Dr Michael Fehlings and Dr Marcel Dvorak have received funding from the Rick Hansen Institute. Dr Vanessa Noonan is an employee of the Rick Hansen Institute. Dr Alexander Vaccaro, Dr Eyal Itshayek and Dr Fin Biering-Sorensen declare no conflict of interest.

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Supplementary Information accompanies the paper on the Spinal Cord website (<http://www.nature.com/sc>).