ORIGINAL ARTICLE

Standardization of data analysis and reporting of results from the International Spinal Cord Injury Core Data Set

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Objectives: The objective of this study was to provide guidelines for reporting results using the International Spinal Cord Injury (SCI) Core Data Set.

Setting: International.

Methods: A committee was created on request of the chair of the Executive Committee for the International SCI Data Set committees. The committee developed a draft consisting of set of recommendations, which were then reviewed and approved by the entire Executive Committee.

Results: Age at injury is recommended as reported by the mean, s.d., median and range. When grouped, 15-year increments are recommended as follows: 0–15, 16–30, 31–45, 46–60, 61–75 and 76+ years. For pediatric SCI, 0–5, 6–12, 13–15, 16–21 years are recommended. Time since injury should be reported by mean, s.d., median and range. The following intervals are recommended: <1 year, 1–5, 6–10, 11–15 years, and 5-year increments thereafter. Calendar time (years during which the study is conducted) is recommended grouped by either 5 or 10-year increments with years ending in 4 or 9. For 'length of stay', the mean and s.d., as well as the median is recommended for report. Severity of injury is under ordinary circumstances recommended, reported in five categories: C1–4 American Spinal Injury Association Impairment Scale grade (AIS) A, B or C; C5–8 AIS A, B or C; T1–S5 AIS A, B, or C; AIS D at any injury level; and ventilator dependent at any injury level or AIS grade.

Conclusion: It is expected that these recommendations can facilitate a more uniform reporting of the very basic core data on SCI. This will facilitate comparison between different SCI studies.

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Introduction

During the 2002 joint meeting of the International Spinal Cord Society and the American Spinal Injury Association, a major new initiative begun to standardize the way that data were collected and were reported for studies of spinal cord injury (SCI).¹ This led to the development of the International SCI Core Data Set.² The Core Data Set includes a minimal amount of very basic descriptive information that would allow comparison of underlying study populations in such a manner that results could be more easily and accurately compared across all studies, and biases within studies could be determined. It was suggested that this descriptive study population information could be presented in the first table of future publications.

No recommendations were provided, however, which would standardize the analysis or the presentation of the International SCI Core Data Set. If different measures of central tendency or groupings of categorical data are used, then results will be difficult to compare across all studies. This problem has been raised by researchers a number of years ago, with the recommendation that an international consensus approach to standards of reporting be developed.^{3,4} Therefore, the purpose of this report is to provide suggested guidelines for the reporting of results using the International SCI Core Data Set.

Methods

The chair of the Executive Committee for the Development of the International SCI data sets (Fin Biering-Sørensen) formed a committee that included the four authors of this paper. The committee met in Florence during the 2009 International Spinal Cord Society meeting to develop this set

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of recommendations, which were then distributed to the entire Executive Committee for review and approval before final submission for publication.

Results

Converting continuous data to ordinal categories raises numerous concerns, and are generally not recommended.⁵ The main concerns are: loss of power, increasing the chance of a false-negative result, underestimating the variation in outcomes between groups and an increased chance of concealing a nonlinear relationship between variables if the categories are too large. Therefore, continuous variables should be analyzed as such unless a nonlinear relationship is suspected. Non-parametric analysis should be used, if appropriate, or transformations should be made that create a normally distributed variable for multivariate studies. In these situations, it is still recommended to report the untransformed mean and median when describing the patient population.

Age at injury

Age should be analyzed as a continuous variable, as suggested above, with reporting of both the mean and s.d. as shown in Table 1. Because the distribution of age at injury

is often skewed, it is recommended that the median and the range also be reported.

When it is desired that age-at-injury data be grouped, 15-year increments are recommended as follows: 0–15, 16–30, 31–45, 46–60, 61–75 and 76+ years. Data would be reported in frequencies and percentages. If sample size is too small for 15-year increments, then it is recommended to continue collapsing the groups without mixing the groups. For example, one might report groupings of 0–30, 31–60, and 61+ years, rather than 0–20, 21–40 years and so on. For studies of pediatric SCI, the following age groups are recommended: 0–5, 6–12, 13–15 and 16–21 years. A separate category for adults over the age of 21 years could be added for comparison purposes, if desired. These pediatric age groups conform to developmental milestones and have been used extensively in previous studies.⁶

For studies that are initiated after reasonable time that has elapsed after injury, it would be more appropriate to report age-at-study initiation coupled with the time after injury, rather than age at injury. The same grouping guidelines should be used as described for age at injury.

Time since injury

Time since injury should be analyzed as a continuous variable, as suggested above. Typically, time since injury would be measured in years. It is recommended that the mean, s.d., median and range be reported as shown in Table 1.

When treated categorically, the following intervals are recommended: <1 year, 1–5, 6–10, 11–15 years, and 5-year increments thereafter. Once again, categories may be collapsed when sample sizes are small, but it is recommended to avoid changing the cut points. Additional categorization within the first year after injury would not ordinarily be necessary, but may be desirable depending on the nature and objectives of the study.

Calendar time

The time frame in which a study was conducted should always be reported, typically as a starting and ending date. When observations are grouped by calendar time, it is recommended to use either 5- or 10-year increments, with years ending in 4 or 9 as the top end of each increment, such as 1990–94, 1995–99, 2000–04, 2005–09, or 1990–99, 2000–09, as shown in Table 1. For multivariate analyses, calendar time may be treated either linearly (with appropriate transformations as needed) or categorically.

Length of stay

Depending on the study design and objectives, length of stay may or may not be a relevant consideration. It would typically be reported in studies of short-term outcomes that are measured during the inpatient stay, at discharge or 1 year after injury. When length of stay is relevant, it is recommended that length of stay be analyzed as a continuous variable, as suggested above. The mean and s.d., as well as the median and range should be reported as shown in Table 1. Length of stay should be treated as a continuous variable in multivariate analyses, with appropriate transformations to improve normality as needed.

Table 1 Study population characteristics

<i>Characteristics</i>		
Age at injury or current age	Mean	s.d.
Age at injury or current age	Median	Range
Years since injury	Mean	s.d.
Years since injury	Median	Range
Length of stay (days)	Mean	s.d.
Length of stay (days)	Median	Range
<i>Year of injury or data collection</i>		
1990–94	<i>n</i>	%
1995–99	<i>n</i>	%
2000–04	<i>n</i>	%
2005–09	<i>n</i>	%
<i>Gender</i>		
Male	<i>n</i>	%
Female	<i>n</i>	%
<i>Neurological category</i>		
Ventilator dependent	<i>n</i>	%
C1–C4 AIS A, B, C	<i>n</i>	%
C5–C8 AIS A, B, C	<i>n</i>	%
T1–S5 AIS A, B, C	<i>n</i>	%
All AIS D	<i>n</i>	%
<i>Place of residence</i>		
Private	<i>n</i>	%
Other	<i>n</i>	%
<i>Associated injuries</i>		
Yes	<i>n</i>	%
No	<i>n</i>	%
<i>Spinal surgery</i>		
Yes	<i>n</i>	%
No	<i>n</i>	%

Abbreviations: AIS, American spinal injury association impairment scale; s.d., standard deviation.

Severity of injury

Under ordinary circumstances, it is recommended that five categories of injury severity be reported: C1–4 American Spinal Injury Association Impairment Scale grade (AIS) A, B or C; C5–8 AIS A, B or C; T1–S5 AIS A, B or C; AIS D at any injury level; and ventilator dependent at any injury level, or AIS grade as shown in Table 1. If there are few ventilator-dependent individuals, they should be grouped with the C1–4 A, B or C patients. If this combined group is still too small, then it is advised to group them together with the C5–8 A, B or C, that is, having three groups C1–8 A, B or C, T1–S5 A, B or C and AIS D at any level.

Studies, in which neurological recovery is the outcome of interest, will typically require separate consideration of each AIS grade rather than the recommended five groups. Moreover, additional groups based on injury level, such as separation of cauda equina injuries may be necessary. If the sample sizes permit, multivariate analyses should begin by considering each AIS grade separately. AIS grades could then be collapsed based on similarity of results. In most instances, injury levels should initially be grouped as C1–4, C5–8 or T1–S5, but could again be collapsed based on the similarity of results. Ventilator dependency should be considered as a separate predictor variable in multivariate analyses.

Ultimately, the choice of appropriate injury severity categories may depend on the nature and purpose of the study. For example, in a study of autonomic dysreflexia, it might be more desirable to categorize patients as having an injury at T6 or above versus T7 or below. A study of pressure ulcers might compare neurologically complete (AIS A) with sensory incomplete (AIS B, C or D).

Other Core Data Set factors

Standardized reporting of the remaining factors in the Core Data Set is equally important and relatively straightforward as appears in Table 1. Gender would be reported as the frequency and percentage of males and females. At minimum, place of residence should be reported as frequency and percentage of private residence versus all others, or can be further categorized as the sample sizes permit. Frequency and percentage of associated injuries and surgery should also be reported whenever those items are relevant.

Discussion

It must be emphasized that these proposed analytical standards are recommendations designed to facilitate comparisons across studies by promoting a common way to report basic study sample characteristics and results. They are not mandates. Individual investigators must use their best judgment regarding how to analyze their data and report their findings. Sample sizes may require collapsing of recommended categories to enhance reliability of findings and precision of estimates. Unique circumstances and specific topics of investigation may require a different approach than proposed herein. However, unless there are compelling reasons to do otherwise, these recommendations should be followed. Even though data are collected in a

standardized way, the ultimate goal of the International SCI Data Sets will not be achieved unless the data are used and reported in a standardized way whenever possible.

For continuous variables (age, time since injury and length of stay), it has been recommended to report the mean, s.d., median and range for all studies. Because the parametric properties of these variables will differ between studies, all four measures are necessary to describe these distributions and allow comparison of study results. Showing all four parameters gives a reasonable idea of skewness. Additional measures of central tendency or distribution, such as the interquartile range, can also be reported if the investigator believes that these measures would be useful in assessing study population representativeness or results.

Exploratory analyses (not published) for several major outcome studies as well as the clinical practice guideline on outcomes after SCI revealed that the recommended injury severity groups produced the greatest discrimination of outcomes.^{7,8,9} Interestingly, no differences in outcomes were found in these studies for persons with thoracic versus lumbosacral injuries.

The reason to have the ventilator-dependent individuals separate is because their outcomes are typically worse than those persons with high tetraplegia who are not ventilator dependent.^{10,11,12} The reason to keep the individuals with AIS D separate, regardless of the level of spinal cord lesion, is because this group has very different outcomes compared with those with AIS A, B or C lesions. Individuals in the AIS D group will often be ambulatory, and have better bladder and bowel function.^{7,8,9,11}

These consensus recommendations are based on our current knowledge of the epidemiological and treatment outcomes of SCI. However, new research may reveal better methods of grouping data that produce more homogeneity within groups and/or better discrimination of outcomes between groups. The Executive Committee for the International SCI data sets will review these recommendations in light of newly published research every few years and will revise these recommendations as needed. Any revised recommendations will be submitted to 'Spinal Cord' journal as a letter to editor, and will be posted on both the International Spinal Cord Society and American Spinal Injury Association websites.

It is hoped that these recommendations can facilitate a more uniform reporting of the very basic core data, which is needed in virtually all studies on SCI, here exemplified by the data collected according to the International SCI Core Data Set.² This uniform reporting will greatly facilitate comparison between different SCI studies.

Conflict of interest

The authors declare no conflict of interest.

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