RELIABILITY AND VALIDITY OF THE INTERNATIONAL STANDARDS FOR NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY IN PATIENTS WITH NON-TRAUMATIC SPINAL CORD LESIONS

PROJECT

PATIENTS AND METHODS

All patients with non-traumatic SCI consecutively admitted to three Italian SCI centers (IRCCS Fondazione Santa Lucia, Montecatone Rehabilitation Hospital and Istituti Clinici Scientifici Maugeri IRCCS of Pavia) between January 1st 2017 and June 30th 2020 have been prospectively enrolled in the study.

The study has been registered at Clinicatrials.gov.

The study was approved by the ethic committee of IRCCS Fondazione Santa Lucia and all the patients signed an informed consent to the study.

Inclusion criteria were: having a non-traumatic SCI in the acute / subacute phase with any level and severity (ASIA Impairment Scale) of injury and having a cognitive status that allows collaboration in the exam.

Exclusion criteria were the presence of dementia or cognitive decline; having a pathology of the peripheral nervous system that may affect the evaluation of ISNCSCI; having a multiple sclerosis.

The following data were prospectively recorded:

- Recording of demographic and clinical history data. Concerning the onset of lesion, for the ischemic and inflammatory groups reference was made to the appearance of the first symptoms,

while for the neoplastic and spondylogenetic myelopathies we referred to the date of surgical intervention which is usually accompanied by a worsening of the clinical picture.

- Evaluation of neurological conditions according to the International Standards For Neurological Classification of Spinal Cord Injury (ISNCSCI) (Revision 2015) (23) with registration of right and left motor and sensory level and of the Neurological Level of Injury (NLI), of the total motor score (MS), of upper extremities (UEMS) and lower extremities (LEMS) motor scores, light touch and pin prick sensory scores, and ASIA Impairment Scale (AIS). This assessment was carried out by two different experienced examiners (Table 1) in each center, 48-72 hours apart. One of the two examiners also assessed the functional status of the patients through the Spinal Cord Independence Measure (SCIM) version 2 or 3 (24).

- The patients were evaluated at admission with the possibility of repeating the evaluation also during rehabilitation stay and at discharge,.

Statistics

Descriptive statistics: mean and standard deviation (SD) for quantitative data; frequencies and percentages for qualitative ones. Normality of data was assessed by Shapiro-Wilk test. The NLI and the AIS grade have been transformed into numbers and treated as ordinal variables. For the NLI the level C1 corresponds to 1, and the level S4-5 to the number 29. For the AIS grade A correspond to 1 and grade E to 5.

Validity and reliability represents the main measurement psychometric properties of instruments. The validity of instrument means that it measures what it is intended to measure. (25) while reliability refers to its stability over time (26).

Different aspects of reliability were assessed with appropriate tests: correlation (Spearman), test-retest reliability (Krippendorf's Alpha) and internal consistency (Cronbach's Alpha) (27, 28). For motor and sensory scores, we also compared the data of the two examiners by means of Wilcoxon matched pair test to evaluate if there was any significant difference.

As to the levels of injury (Neurological Level of Injury, left and right sensory and motor level of injury) and AIS grade the agreement between the two examiners regarding was assessed through the Krippendorff's Alpha. Furthermore, for the assessment of the levels, we compared the levels established by the two examiners, by counting the difference (1 level, 2 or move levels) in cases where assessments differed.

We evaluate psychometric properties of AIS scale on all sample and in each pathology subgroups.

As currently there is no gold standard for the neurological evaluation of persons with SCI other than the ISNCSCI, we have evaluated the convergent construct validity of the Standards through a Spearman correlation between the total motor scores, the upper and lower extremities motor scores and the total SCIM score as well as the subscores "Self-care" and "Mobility". This correlation was performed by means of Spearman test.

58 According to Landis and Koch (29), we interpreted ICC values and the level of agreement by
59 Kappa-values as follows:
60 0–0.1-virtually none
61 0.1–0.4-slight
62 0.41–0.6-fair
63 0.61–0.8-moderate
64 0.81–1-substantial
65 All analyses were performed with SPSS 22.
66 Significance was set at $p<0.05$
67 Data have been reported according to the Guidelines For Reporting Reliability And Agreement
68 Studies (GRRAS) (supplemental material, Table 15).