Validation of the Walking Index for Spinal Cord Injury (WISCI) in a USA and European Clinical Population

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ABSTRACT

Objective: To demonstrate the prospective construct validity of the WISCI in USA/European clinical population

Design: Prospective Cohort in Denmark, Germany, Italy and USA

Participants/Method: Patients with acute complete/incomplete (ASIA A, B, C, and D) traumatic spinal cord injuries (SCI) were enrolled from 4 centers. Lower extremity motor scores (LEMS), WISCI levels, and locomotor Functional Independence Measure (L-FIM) scores were assessed with change in ambulatory status. WISCI progression was assessed for monotonic direction of improvement (MDI). LEMS were correlated to WISCI and L-FIM. Use of walking aids/braces were analyzed.

Results: One hundred seventy subjects were enrolled and 15 subjects dropped out. Of the 155 subjects (USA 112/155; Europe 43/155) (ASIA Impairment Scale (AIS) ASIA A=59, B=19, C=33, D=44), assessments were performed initially and at final assessment (3 - 12 months post injury) or maximum WISCI score of 20. Motor complete subjects (ASIA A/B) 84 % (66/78) and incomplete subjects (ASIA C/D), 17% (13/77) showed no progression. Both ASIA A/B/C/D subjects (61/76) and ASIA C/D (51/64), who improved, 80% demonstrated MDI. Of those ASIA C/Ds, who did not show MDI, only one assessment in 10/13 subjects failed to demonstrate this. LEMS correlated with WISCI at initial and final assessment (0.74 & 0.68 $p < 0.001$). Walking aids use/patterns of care differed between USA/Europe.

Conclusion: The results support the hierarchical ranking of the WISCI scale and the correlation of WISCI levels to impairment (LEMS) in a clinical setting of 4 nations. Differences in practice between USA and Europe need consideration in design of trials.

INTRODUCTION

Outcome measures for use in clinical trials for spinal cord injury (SCI) to establish efficacy must be valid and reliable[1]. The Walking Index for Spinal Cord Injury (WISCI) was introduced in 2000[2] and modified[3] the following year as a walking capacity measure, which incorporates the use of walking aids, braces and physical assistance on a 21 level scale. It was ranked by an international group of SCI clinicians and investigators from the most impaired to least impaired level and demonstrated construct (theoretical) and face validity. It subsequently was compared to 4 other scales in a clinical population of mixed SCI and spinal cord lesions for demonstration of retrospective criterion validity (compared to other scales)[4]. Recently, it was utilized in a multicenter randomized clinical trial, assessed by blinded observers, and showed high correlations with lower extremity motor scores, balance, walking speed, six minute walk and locomotor FIM illustrating prospective criterion validity[5]. The rationale of this prospective study was first; to demonstrate the validation for the formulation of the hierarchical ranking in more than one center and second; to show a correlation of WISCI levels with the motor score (impairment). The purpose was to show that the 21 level scale would follow a monotonic progression and correlate with LEMS at the initial and final assessment.

PARTICIPANTS AND METHOD

A) The United States (USA) group:

Eligible participants included all acute complete and incomplete (ASIA A, B, C and D) traumatic spinal cord injuries C2- L3, admitted within one month of injury that could be followed for 6-12 months. Exclusion criteria included significant head injury, upper or lower extremity fracture, or presence of an immobilization device that interfered with accurate assessment and/or ambulation.

To validate the hierarchical ranking of the WISCI, LEMS (blinded), the WISCI and FIM were recorded for comparison with change between initial evaluation and final evaluation. The change was recorded by a digital photograph for future independent analysis, which has been previously reported for reliability[6]. The type of walking was classified in the photo by the type of walking aid, braces and physical assistance and adjudication was required for those events that did not fit the WISCI scale. Inter-rater reliability was determined by three physical therapists (who did not treat the patients) from the photos and showed a correlation of 0.91.

Descriptive data were recorded for the type of walking aid (parallel bars, standard or rolling walker, forearm or axillary crutches), braces (short leg, long leg or equivalents such as ankle ace bandage, knee stabilizer) and canes. Physical assistance of one ranged from contact guarding to not equal or greater than moderate assistance (min/mod).

B) European Group (Denmark, Germany and Italy)

The inclusion/exclusion criteria were similar to the USA group. Descriptive data for use of parallel bars, walkers, crutches and canes were collected to compare frequency of use between European centers and the USA. Photo documentation for WISCI levels was not able to be applied uniformly at each of the centers. Physicians performed the neurological assessment and therapists did the FIM and WISCI assessments independently.

Statistical Analysis

Descriptive analysis of the monotonic (one direction) progression of subjects was performed. Pearson correlations were performed for changes in LEMS and WISCI levels from the initial assessment to one year follow up or until subjects reach a level of 20 on the WISCI scale. Spearman correlations were performed for initial LEMS/WISCI/L-FIM levels and final LEMS/WISCI/L-FIM levels. In addition, the frequency of the 7 Locomotor FIM levels will be compared to the 21 WISCI levels for all assessments.

RESULTS

Table 1. *LEMS and L-FIM scores compared to WISCI scores at Initial and Final Evaluations for Patient Progression in USA and Europe*

Correlations

	Total Group			Europe			U.S.A.		
	R	*P*	*N*	*R*	*P*	*N*	*R*	*P*	*N*
LEMS vs. WISCI Initial	0.77	<0.01	156	0.73	<0.01	40	0.78	<0.01	115
LEMS vs. WISCI Final	0.89	<0.01	161	0.84	<0.01	40	0.9	<0.01	120
LEMS vs. WISCI Final (for those who progressed)	0.72	<0.01	73	0.47	0.74	15	0.8	<0.01	58
FIM vs. WISCI Initial	0.59	<0.01	150	0.7	<0.01	40	0.67	<0.01	111
FIM vs. WISCI Final	0.59	<0.01	161	0.58	<0.01	40	0.63	<0.01	120
FIM vs. WISCI Final (for those who progressed)	0.69	<0.01	73	0.71	0.002	15	0.7	<0.01	58
LEMS impr. vs. WISCI impr.	0.61	<0.05	158	0.6	<0.05	40	0.62	<0.05	113
LEMS impr. vs. WISCI impr. (for those who progressed)	0.49	<0.05	73	0.35	N.S.	15	0.54	<0.05	58

Figure 1. *Monotonic Progression by ASIA Impairment in the USA*

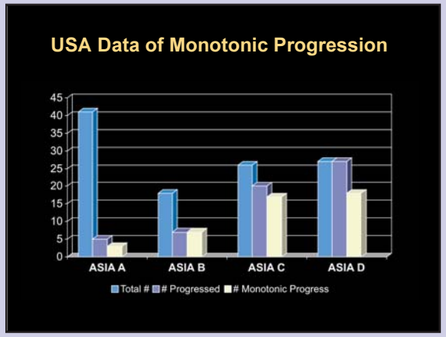


Figure 2. *Monotonic Progression by ASIA Impairment in Europe*

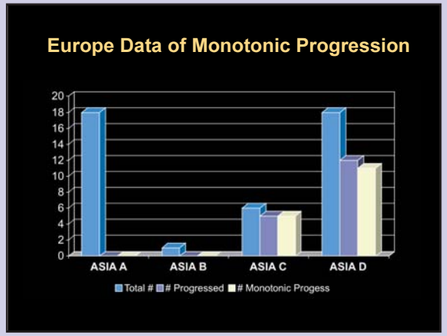


Figure 3. *Monotonic Progression by ASIA Impairment for Total Group*

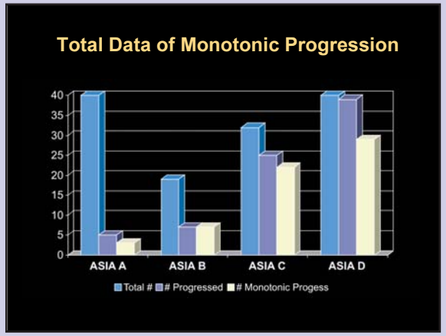
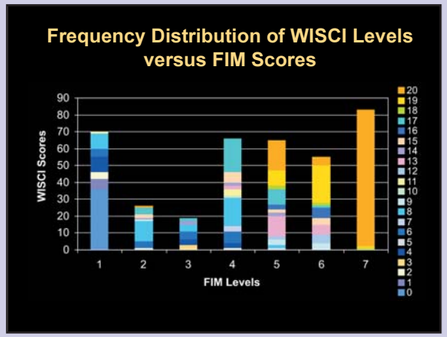


Figure 4. *Frequency Distribution of WISCI Levels versus FIM scores*



Use of Braces

- The majority of subjects in Europe 14/19 (73%) and USA 32/63 (51%) did not use braces during their rehabilitation. In the USA, either one or two short leg braces (or their equivalent) were recorded most often, 31/46 (67%) as compared to some combination of long leg braces.

Use of Walking Aids

- The use of walking aids of all types in Europe 15/20 (75%) and the USA 46/55 (83%) was similar. In Europe, the use of parallel bars was recorded more frequently (Europe 60% versus USA 29%).

DISCUSSION

These findings support the first hypothesis of monotonic progression for a prospective cohort of consecutive admissions of traumatic subjects with SCI to a regional center in the United States and 3 centers in Europe. Only 11.5 % of cases deviated from the hierarchy established in the original WISCI report and subsequently modified. The European Centers showed a higher proportion of monotonic progression (94 % vs 80%), but the assessments were less frequent and the health care delivery system differs. In the USA, length of stay is shorter than Europe (typically 4-6 weeks for paraplegics and 8-10 weeks for tetraplegics versus 4 months for paraplegics and 6 months for tetraplegics)[7, 8, 9]. Therefore in the USA, therapists are required to progress patients more aggressively. They may advance a subject without a device one week and then restore the device the following days/week as was seen in 7/10 subjects. This difference in practice should be considered in planning an international trial involving different nations with different health care systems.

The second hypothesis is based on a clear relationship of WISCI levels with the severity of the motor impairment as determined by lower extremity motor score. The recent randomized clinical trial[5] of locomotor training for 146 subjects assessed by blinded observers from 6 centers showed an average LEMS of 45/50 and a WISCI of 18/20 at 6 months and a high correlation of LEMS to WISCI levels at 3, 6 and 12 months for both the experimental and control arms combined[10]. The correlation of WISCI levels to LEMS at initial assessment and final assessment was highly significant ($p < 0.001$) in this prospective study and supports our second hypothesis.

Because the use of parallel bars and walkers appear to differ between USA and Europe, the application of the WISCI scale may need standardization for a clinical trial involving different countries and cultures. While L-FIM and WISCI scores correlated at the initial and final assessment, multiple WISCI scores for the same FIM levels such as 5 may reflect health system requirements.

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