Prospective Validity/Response to Change of the Walking Index for Spinal Cord Injury (WISCI) in a Multicenter Randomized Clinical Trial (MRCT)

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ABSTRACT

Objective: To demonstrate the prospective validity and response to change of the WISCI scale and other walking measures in the Spinal Cord Injury Locomotor Trial (SCILT).

Design: Prospective Multi-center Randomized Clinical Trial (MRCT) of a walking intervention for subjects with acute traumatic spinal cord injury (SCI).

Participants/methods: Body Weight Support Training (BWST) was compared to a controlled arm for 146 subjects with incomplete SCI (C-4 - L-3) enrolled within 8 weeks of injury and treated for 12 weeks. Primary outcome measures (OM); Locomotor Functional Independence Measure (LFIM), time to walk 50 feet (50-ft time) and 6-minute walk, tested at 3, 6 and 12 months. In addition, secondary OM; Lower Extremity Motor Scores (LEMS 0-50), Berg Balance Scale (BBS max56), WISCI (0-20), and LFIM (1-7) were performed at each of 5 centers by blinded observers. Because no significant difference between arms was previously reported, correlations of primary/secondary OM were performed on the combined data.

Results: Correlations of change from baseline to 6 months of WISCI to LFIM= 0.88, (n=110); BBS= 0.84, (n=111); LEMS= 0.60, (n=112) and FIM= 0.48, (n=111). Correlations at 6-months of WISCI level with 50-ft time= minus 0.59, (n=88) and with 6-minute walk=0.75, (n=93).

Conclusion: The prospective validity/response to change of the WISCI scale is supported by the significant positive correlations with LFIM, BBS, LEMS, 6-minute walk and a negative correlation with time to walk 50 feet in a MRCT. The BBS correlated higher than the LEMS with the WISCI, which has not been previously reported.

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PURPOSE

The recovery of walking function after spinal cord injury (SCI) for individuals with incomplete injuries is one of their primary goals (Patrick 2003) and has become a major focus in the design of recent clinical trials (Dobkin 2003, 2006) and outcome studies (Ditunno 2000, 2001, van Hedel 2005). If neurological recovery after SCI is a major goal of regeneration strategies by scientists, then the behavioral/functional recovery such as walking is essential to the restoration/rehabilitation plan of clinicians and consumers. Valid outcome measures to determine the effects of these interventions in clinical trials, therefore, must examine both improvement in the impairment (neurological) and the behavior (functional capacity) (Curt 2004, ICCP 2006).

Use of more global disability (SCIM 2006) scales, particularly in large data bases (Model Centers 1995, 1990) have characterized mobility outcomes as performed in the environment, which often mimic real life situations and may have different terrains and living conditions. While disability measures are important assessments for trials and clinical goal setting, they may show improvement solely due to training (complete paraplegia is trained to be independent in a wheelchair), with no improvement in motor scores. Walking functional capacity scales, walking speed (Kim 2004) and walking efficiency, however, test walking under standardized environmental conditions and show good correlations with recovery of lower extremity strength (Kim 2004, van Hedel 2005) .

The Walking Index for Spinal Cord Injury (WISCI), which was developed as a 21 level functional capacity scale, integrates physical assistance in addition to braces and walking aides (Ditunno 2000, 2001). The distinction between a walking functional capacity scale and a disability scale that tests individuals in the environment may be important to clinical trials, to demonstrate improvement in neurological recovery, because a functional limitation/capacity measure may be more sensitive to changes in improvements of strength. A recent prospective randomized clinical trial (RCT) to evaluate the effect of locomotor training following SCI (Dobkin 2006 SCILT Trial) utilized multiple endpoints (outcome measures) to assess the improvement in walking function. These endpoints reflected the changes in the physical impairment (increased strength), the walking functional capacity (balance, WISCI , walking speed, walking distance) and the walking disability, locomotor scale (FIM-L) total disability (FIM).

The purpose of this poster is to validate the responsiveness of the WISCI scale to improvements in the physical impairments and other measures of walking functional capacity and disability, when utilized in a prospective clinical trial by blinded observers at multiple centers (Dobkin 2003, 2006).

SUBJECTS AND METHODS

Participants/methods: Body Weight Support Training (BWST) was compared to a controlled arm for 146 subjects with incomplete SCI (C4 - L3) enrolled within 8 weeks of injury and treated for 12 weeks. Primary outcome measures (OM); Locomotor Functional Independence Measure (LFIM), time to walk 50 feet (50-ft time) and 6-minute walk, tested at 3, 6 and 12 months. In addition, secondary OM; Lower Extremity Motor Scores (LEMS, 0-50), Berg Balance Scale (BBS, 0-56), WISCI (0-20), and LFIM (1-7) were performed at each of 5 centers by blinded observers at 3, 6 and 12 months. Because there was no significant difference between arms was previously reported (Dobkin 2006), correlations of primary/secondary OM were performed on the combined data. Response to change and predictive validity was also assessed.

RESULTS

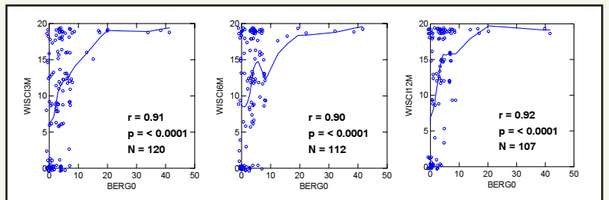
Table 1. *Baseline measurements for UMN and LMN subjects in intention-to-treat analyses.*

	B + C			C + D		
	BWSTT	CONT	*p*	BWSTT	CONT	*p*
No.	52	57		35	33	
Age, y	26 (16–68)	24 (16–61)	0.32	36 (17–69)	23 (17–61)	0.06
Gender			0.24			0.26
% Male	85	74		83	70	
% Female	15	26		17	30	
Race						
% White	48	68	0.08	51	58	0.30
% African American	34	19	40	21		
% Hispanic	10	11	6	15		
% Asian	6	0	3	0		
% Other	2	2	0	3		
Level						
% Cervical	67	54	0.33	66	55	0.54
% Thoracic	19	23	14	24		
% Lumbar	14	23	20	21		

Values are median (range). Group B + C includes all subjects used for intent-to-treat analyses of FIM-L score. Group C + D includes all subjects used for the intent-to-treat analyses that were able to walk.

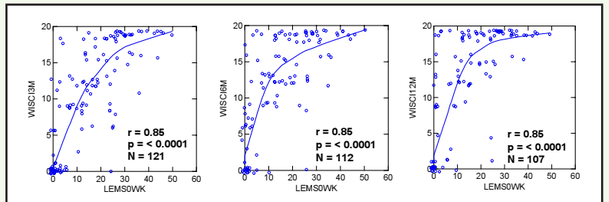
Table 1 from Dobkin 2006

Figure 1. *Comparison of WISCI to Berg Balance Scale at 3, 6 and 12 months.*



Comparison of WISCI to Berg scores at 3, 6, and 12 months showed a highly significant correlation for >100 subjects. Demonstrates validation of the WISCI with another functional capacity scale (BBS).

Figure 2. *Comparison of WISCI to LEMS at 3, 6 and 12 months*



Comparison of WISCI to LEMS scores at 3, 6, and 9 months showed a highly significant correlation. Demonstrates validation of the WISCI with an impairment scale (LEMS).

Table 2. *Spearman correlations of WISCI at 3, 6 and 12 months to Total FIM (FIMT), Locomotor FIM (FIMS), Berg Balance Scale (BERG), Lower extremity motor scores (LEMS), Speed of 50 foot walk (SPED) and 6 minute walk (WK6M). The negative correlation for "speed" reflects the decrease in time to walk 50 feet. All values are significant at p<.001. Number of subjects ranged from 80-121.*

	FIMT3MO	FIMS3MO	BERG3M	LEMS3MO	SPED3MO	WK6M3MO
WISCI 3 Mos	0.73	0.92	0.91	0.85	-0.78	0.86
	FIMT6MO	FIMS6MO	BERG6M	LEMS6MO	SPED6MO	WK6M6MO
WISCI 6 Mos	0.77	0.89	0.90	0.85	-0.85	0.79
	FIMT12MO	FIMS12MO	BERG12M	LEMS12MO	SPED12MO	WK6M12MO
WISCI 12 Mos	0.74	0.88	0.92	0.88	-0.77	0.84

Figure 3. *Spearman correlation over time of measures to determine predictors of WISCI levels at 12 months.*

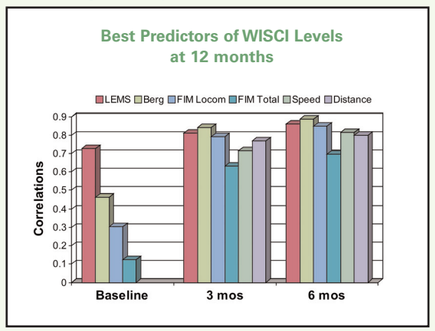


Figure 4. *Comparison of WISCI to Locomotor FIM at 3 months. Note that the range of WISCI levels is 8 to 19 for a LFIM of 6 and for LFIM = 5 (WISCI= 6-18).*

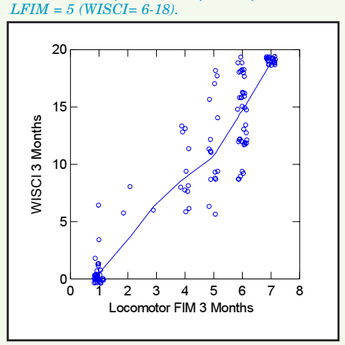
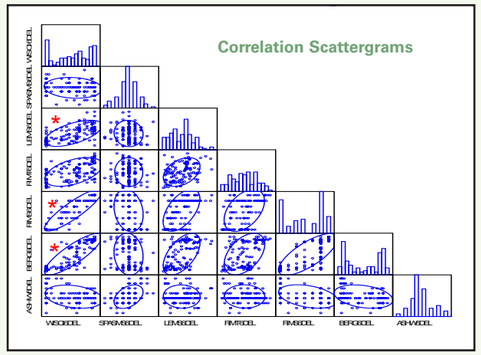


Figure 5. *Comparison of WISCI to Lower Extremity Motor Scores (LEMS) at 3, 6 and 12 months.*



DISCUSSION/CONCLUSIONS

The theoretical purpose of the WISCI scale by the original investigators (Ditunno 2000) was to develop a "more precise quantification of improvement in functional limitation (capacity) secondary to improvement in impairments". It was not designed to reflect improvements in physical assistance alone. The results of this randomized multicenter clinical trial demonstrate the theoretical validity of the purpose stated above in several different analyses.

First, the very high correlations of the WISCI to the impairment (LEMS r = 0.85) and other functional capacity measures (BBS r = 0.90, LFIM r = 0.89, Speed r = 0.85, Distance r = 0.79) in the trial supports the concurrent criterion validity. Second, the correlation over time of predictors of the 12 month WISCI levels shows the LEMS (impairment) is the best predictor at base line. This supports predictive criterion validity.

Third, the high correlations of the walking measures with the WISCI are evidence of convergent validity, but the poor correlations with spasms and Ashworth are evidence of divergent validity.

Finally, while the LFIM correlates highly with the WISCI and other walking measures a scattergram of the WISCI plotted against the LFIM reveals multiple WISCI levels for LFIM 5 (WISCI = 6 to 18) and LFIM 6 (WISCI = 9-19). It should be obvious to a consumer/staff person based on clinical intuition that walking with one cane alone with no brace or physical assistance (WISCI = 19) is clinically superior to walking with a walker and braces (WISCI = 9), which are both graded as LFIM = 6 or walking with a device(s).

CONCLUSION

The concurrent and predictive criterion validity of the WISCI scale has been supported in this prospective multicenter clinical trial by the significant correlations of outcome measures assessed by blinded observers. LEMS are the best baseline predictor of WISCI levels at 12 months with the BBS slightly better at 3 and 6 months.

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