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The Walking Index for Spinal Cord Injury (WISCI/WISCI II): nature, metric properties, use and misuse.

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TILE

The Walking Index for Spinal Cord Injury (WISCI/WISCI II): nature, metric properties, use and misuse.

RUNNING TITLE: WISCI/WISCI II: Metric Properties, Use/Misuse

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STRUCTURED ABSTRACT

Study design: Literature review

Objective: To critically review all publications/internet sites that have described/used the Walking Index for Spinal Cord Injury (WISCI II), as a measure of impairment of walking function after spinal cord injury (SCI), in order to identify its psychometric properties, clarify its nature, specify misuse, and incorporate the findings in an updated guide.

Method: A systematic literature search was done of Ovid MEDLINE, CINAHL, PsychINFO, Cochrane Central Register of Controlled Trials, Scopus, and electronic sites using key words: WISCI or WISCI II, SCI, paraplegia/ tetraplegia/ quadriplegia, ambulation/gait/walking. Among 1,235 citations retrieved, 154 relevant articles/sites were identified, classified and examined by the authors; recommendations were made based on findings.

Results and Discussion: The validity (face/concurrent/content/construct/convergent/criterion) and reliability of the WISCI II has been documented in clinical trials, clinical series, and considered adequate by systematic reviewers. In chronic SCI subjects, reliable determination of the maximum (as opposed to self-selected) WISCI II level requires more time and experience by the assessor. The correct use of WISCI II is clarified for testing acute/chronic phases of recovery after SCI, age of subjects, devices and settings. The WISCI II and walking speed measures may be performed simultaneously.

Conclusion: The increased use of the WISCI II is attributed to its unique characteristics as a capacity measure of walking function and its strong metric properties. Appropriate use of the WISCI II was clarified and incorporated into a new guide for its use. Combining it with a walking speed measure needs further study.

INTRODUCTION

The Walking Index for Spinal Cord Injury (WISCI) is an ordinal scale that captures the extent and nature of assistance (combinations of orthoses, supporting equipment such as walkers, and human helpers) that persons with spinal cord injury (SCI) require to walk. The original 19 levels, from unable to walk in spite of all possible supports, to being able to walk without any, were rank-ordered by a panel of SCI experts to reflect gradations of impairment and their relationship to walking function.[1] The WISCI scale was modified the following year to the WISCI II with the addition of two levels.[2] Since its introduction, it has enjoyed increased popularity[3] and acceptance[4] as a capacity measure of walking function for use in clinical trials.

International SCI experts[5,6] have, however, recommended that the WISCI II,[2] be combined with the Ten Meter Walk Test (10MWT), another validated tool for quantifying walking function. Systematic reviews of the medical literature confirm the validity of the WISCI/WISCI II[7] and its use together with the 10 MWT for assessment of ambulatory function.[8]

It has been recommended by some, nonetheless, that the WISCI II undergo further evaluation.[6,7,9] Recent studies[10-12] have demonstrated reliability, and the relationship of WISCI II to both the severity of the injury and to walking speed. These studies also showed the need to progress subjects systematically[10,11] from their community (self selected) WISCI II level (performance, in the terminology of the International Classification of Functioning, Disability and Health (ICF)[13] to their maximum level (capacity, in ICF terms), which has not been clearly stated in existing instructions to clinical investigators[14-16] and does require additional time, and training for obtaining accurate assessments.

Our purpose here is to critically review all publications and internet sites that have described and/or used the WISCI/WISCI II, in order to identify and clarify the nature, psychometric properties, correct use and misuse of the WISCI II. Recommendations for proper use, stemming from this review,

24 are incorporated into an updated guide (Appendix 1: WISCI II Guide: Instructions for Use) suitable for

25 use by clinical investigators and dissemination in the literature and appropriate websites.[17]

26

27 **METHOD**

28   A systematic search was performed of all papers as well as websites mentioning WISCI/WISCI II.

29 The literature search was conducted with the assistance of a senior librarian from May to August, 2011

30 and identified papers published from 2000 to August 2011 that explicitly mentioned the WISCI/WISCI II,

31 and/or articles that dealt with the measurement of walking capacity in patients with SCI. Databases

32 included Ovid MEDLINE, Ovid MEDLINE In-Process & Other Non-Indexed Citations, CINAHL,

33 PsychINFO, Cochrane Central Register of Controlled Trials, and Scopus, which includes Embase

34 citations. All study designs, including case reports, were included, with no restrictions on the ages of

35 participants. Non-English articles and animal studies were excluded. The following search terms were

36 used: WISCI/WISCI II, SCI, paraplegia/tetraplegia/quadriplegia, ambulation/gait and walking/walking

37 capacity. Citations were then imported into a RefWorks© database and duplicates removed, leaving

38 1,235. In addition, other data bases such as Google and a hand search of *Spinal Cord* yielded twelve

39 citations not identified by the above strategy.

40   Two authors (GS & JFD) independently identified and classified the papers and (as applicable)

41 their study design, which included both SCI and WISCI/WISCI II through a review of the abstracts, texts

42 and references. A third author (PLD) reconciled differences and prepared results for circulation to the

43 authors' panel and subsequently to external reviewers. This yielded 168 citations from all sources, of

44 which 14 were subsequently excluded as non-English, involving diseases other than SCI or animal

45 research, for a total of 154 relevant references.

46   The list of 154 citations with their assigned classification is published as supplementary material.

47   Sixteen of the 154 study citations examined underlying mechanisms of physiological changes and

48   referenced the WISCI II scale. Ten of these 16 studies correlated changes in WISCI II scores with

49   neurophysiological parameters, whereas 6 cited the WISCI/WISCI II only in the bibliography or for

50   purposes of classification of the subjects.

51   Relevant citations included six systematic reviews of outcome measures for SCI, which referenced

52   WISCI/WISCI II. Two reviews [7,8] assessed the validity and other psychometric properties of outcome

53   measures for ambulation, including the WISCI II. Other reviews targeted measures of disability,[18]

54   general function or mobility[19] or merely reference the WISCI II in studies on body weight

55   supported/robot-assisted gait training.[20,21] Articles[7,9] that identified limitations of the WISCI/WISCI II

56   were studied carefully for issues related to the WISCI/WISCI II requiring clarification. Afterwards, the

57   guide for suggested future use of the WISCI II was edited by a coauthor (MSR) who has trained clinical

58   investigators in previous clinical trials in Asia, Europe and USA. The final guide was reviewed by the

59   panel of authors and by outside reviewers for comment and approval. The outside reviewers were chosen

60   to provide balance and reduce bias; Tania Lam and Hubertus van Hedel, who had published most of

61   criticisms[7,30] discussed in this manuscript.

62   A panel composed of authors of the WISCI/WISCI II identified the following issues for further

63   analysis and discussion: the nature of the WISCI/WISCI II, the relationship of severity of injury to

64   walking capacity, the validity, reliability and responsiveness of the scale and its correct use (see below).

65

66   **RESULTS AND DISCUSSION**

67   **1. Nature of the WISCI II**

68   The WISCI II is unique as a walking capacity scale for individuals with SCI who have the

69   capacity "to stand and walk," for several reasons. First, it has standard criteria for the testing environment

70   and subjects are progressed systematically through a validated sequence of capacity levels,[22] incorporating

71   devices and personal assistance, to their **maximum** walking capacity. Second, WISCI II ranks levels

72   according to the severity of underlying impairment rather than the need for physical assistance, walking

73   aids, or braces (or their equivalent). The relationship between the severity of the impairment, reflected in

74   the strength of leg muscles (lower extremity motor scores), and the WISCI II has been demonstrated in

75   acute[23] and chronic[11] subjects with SCI. In fact, in subjects with acute SCI, the initial (baseline) lower

76   extremity motor score (LEMS) is the best predictor of WISCI II score at 12 months post SCI onset,

77   explains most of the variance in the WISCI II, and has high correlations with WISCI II improvement at 3,

78   6, 9 and 12 months.[23] The strength of these correlations differ based on whether subjects are paraplegic or

79   tetraplegic, the demographics of the population studied, and whether subjects have acute or chronic

80   injuries.[11,24] Factors other than LEMS such as pain, spasticity or balance also contribute to walking

81   function. Training plays a major role in improvement in walking function for subjects with chronic SCI,

82   in whom leg strength has been maximized and plateaued.[24]

83   The WISCI II's levels reflect the underlying impairment and should not be dichotomized into

84   dependent and independent levels based on physical assistance, in an attempt to more closely mirror a

85   disability scale. Its unique features differentiate the WISCI II from disability scales, which may fail to

86   identify differences in devices when assigning scores. As an example, the Functional Independence

87   Measure (FIM) assigns a 6 for locomotion to an individual capable of modified independent ambulation

88   regardless of the device(s) used; while the Spinal Cord Independence Measure (SCIM) progresses the

89   ranking of devices from walking frame to one cane without addressing personal assistance at each level as

90   discussed by Patrick.[25]

91   The WISCI II scale is an impairment related capacity scale and the lower extremity motor score

92   explains most of the variance (R2 = 0.85) of the WISCI score at 12 months in a multicenter randomized

93   trial of 146 subjects.[23] Capacity measures of walking function such as the WISCI II and walking speed

94   utilized in research studies require standardized measurements of devices, distance and the environment.

95   However, global disability scales (performance) such as the FIM reflect burden of care and describes what

96   a person routinely does in their environment,[13] which "may differ from individual to individual and from

97   one time to another".[26] Curt[27] reported significant functional improvement in activities of daily living at

98   12 months in 246 ASIA A and B subjects assessed by the SCIM (a global disability scale) with no change

99   in WISCI scores. This improvement is most likely due to training alone (i.e. compensation)[27] since a

100   subject with complete paraplegia may achieve wheelchair independence with no recovery in lower

101   extremity strength. Thus, papers[19,28] that identify the WISCI II as a disability scale place it in the incorrect

102   domain (ICF classification) and are in error.

103

104   *Systematic progression justifies all WISCI II levels*

105   In the original publications[1,2], the ranking of the 21 levels was determined and validated by SCI

106   specialists from 8 countries. Order was determined by the severity of the underlying motor impairment

107   which resulted in some WISCI II levels which require physical assistance but few devices (i.e. reflecting

108   less impairment) being placed higher than other levels where subjects ambulate without physical

109   assistance but more devices. This is one of the characteristics that distinguish the WISCI II as a capacity

110   scale from disability scales which always rank individuals who do not require human assistance higher,

111   regardless of the use of devices. Some publications[29,30] noted that the observed frequency of some WISCI

112   II levels (14 and 17) was low and therefore they might not be needed. It was also noted that the WISCI II

113 instructions require clarification as to how to assess subjects' walking capacity at follow-up after

114 discharge from the hospital.

115 While prior guides[1,14] stated that during the acute period SCI subjects should be assessed at the

116 highest possible level without compromising safety, as determined by a trained therapist; the precise

117 method of systematic progression in chronic subjects has not been stated. Determining the maximum

118 WISCI II level requires that subjects be progressed systematically through each level; as several

119 studies[10,11] have shown that the maximal level may be 3 to 6 levels higher than the patient's self-selected

120 one. Marino's study[10] provides insight into how frequently WISCI II levels 14 and 17 are used during the

121 progression of subjects from their self selected to maximum WISCI II level. Over half (14/26) of subjects

122 progressed to or beyond level 14 during the determination of their maximal WISCI II level and almost a

123 quarter (6/26) progressed to 17 or above. However, only 2 of 26 ended their progress at levels 14 or 17.

124 In chronic subjects the challenge is ensuring that the maximum level has been accurately evaluated.   This

125 method of progression for chronic subjects has been described in recent papers[10, 11] and has been

126 incorporated into the updated guide.[17]

127

128 **2. Psychometric qualities of the WISCI II**

129 *Validity*

130 One of the strongest features of the WISCI II, which has likely contributed to its broad acceptance,

131 is high validity across multiple dimensions. The hierarchical ranking agreed on by the 24 experts in SCI

132 walking function established content and face validity.[1, 2] A subsequent prospective study[22] of 170

133 subjects in four countries confirmed that progression through the levels followed a monotonic pattern in

134 more than 80% of subjects, and the correlation of walking capacity (WISCI II) with impairment (LEMS)

135 was 0.91 (p< 0.001) at final assessment, supporting content and construct validity. Subsequent studies by

136   our group and others have demonstrated criterion-related, predictive and concurrent validity, as well as

137   both convergent and divergent construct validity.[11,22,27,29,31,32] The outcomes of the Spinal Cord Injury

138   Locomotor Trial (SCILT)[23] reported predictive, criterion and concurrent validity: the WISCI II was

139   correlated with LEMS (impairment), balance, walking speed, 6 minute walk (capacity), locomotor FIM (7

140   items) and the total motor FIM (13 items). Others studies have shown a correlation between the WISCI II

141   and mobility measures such as the 10MWT, Timed up and Go (TUG) test,[31,33] 6 minute walk test

142   (6MWT),[32,34] Berg Balance Scale, SCIM and Spinal Cord Injury-Functional Ambulation Profile (SCI-

143   FAP).[33]

144

145   *Reliability and responsiveness*

146   Although the validity of the WISCI/WISCI II has been well established, it has been suggested that

147   further evidence of reliability and responsiveness is needed.[6, 7,18,30] During the development of the WISCI

148   II, a videotape was created of representative patients functioning at each level (40 randomized clips) and

149   circulated to SCI experts. The data collected included 24 individual independent scorings and team

150   scorings. The inter-rater reliability (IRR) was 1.00 for individual participants and the 8 participating

151   teams.[1] However, reliability here involved agreement on the nature and types of physical assistance and

152   aides the person used with walking.

153   A more crucial test for a capacity scale is whether two appropriately trained individuals agree on

154   the same level of maximum capacity after assessing and progressing the same patient independently. In a

155   study of subjects with chronic SCI, Marino and colleagues[10] reported that inter-and intra-rater reliability

156   were both 1.00 for self selected WISCI II level. The intra-rater reliability for maximal level WISCI II was

157   1.00; inter-rater reliability was 0.98. The progression from self selected to maximal WISCI II level also

158   showed good agreement between and within therapists. Recently, Scivoletto[12] reported that inter-rater

159   reliability was 0.98 for 19 acute patients.

160   The WISCI II was initially reported[9] to have limited responsiveness in the period of 0-3 months

161   post SCI onset and poor responsiveness in subsequent periods, however, the study cohort was small (n =

162   22) and consisted of good walkers (70 % with LEMS ≥30). In a more representative sample of 886

163   persons with American Spinal Injury Association Impairment Scale (AIS) A, B, C and D injuries, the

164   same group reported several years later[4] that responsiveness was good in AIS C (N=137) and D (N=223)

165   subjects, and equal to that of the 10MWT at 3, 6 and 12 months after injury.

166   In a study[11] of 76 subjects with chronic SCI, WISCI II reproducibility was excellent, with an

167   intraclass correlation coefficient (ICC) of 0.99 for both the self-selected and maximum WISCI II level.

168   The resulting smallest real differences (SRDs) of 0.79 (self-selected) and 0.60 (maximum) suggest that "a

169   change of one WISCI II level can be interpreted as real in a chronic patient".

170   The study of the psychometric properties of the WISCI II in chronic subjects has been limited to

171   an assessment of reliability, reproducibility and validity in two studies.[10,11] Further validation in chronic

172   subjects is warranted.

173

174   **3. Use and misuse of the WISCI II**

175   Past criticisms of the WISCI II include ceiling effects,[7, 23, 30] floor effects,[7] lack of responsiveness

176   beyond 3 months,[30] lack of clarity regarding the scoring of equivalents of short leg braces (e.g., Alpine

177   boots),[3,30] broad range of physical assistance,[30] redundant categories,[30] and cultural differences in use of

178   walking devices. Several of these, such as responsiveness and low frequency (unneeded) categories, have

179   been addressed above.

180   The ceiling effect and other limitations of walking function were addressed in the original

181   publication[1] by the statement "different distances (household and community), velocity and energy

182   requirements will need to be added". Two studies demonstrating the ceiling effect were reported in 2006;

183   one with 22 subjects[9] who were primarily AIS D, and the SCILT randomized controlled trial (RCT)[23] of

184   144 patients, which included AIS B, C and D subjects. In both studies, the subjects who reached the

185   maximum WISCI II level of 20 were able to show improvement in the speed of walking in subsequent

186   evaluations. Ceiling effects were one of the reasons that studies examining subjects at different distances

187   and speeds were planned.[10,11,35] Most authorities recommend combining the WISCI II with a measure of

188   walking speed to compensate for this shortcoming. The floor effect has been mentioned in one systematic

189   review,[7] based on one study[29] which included a large proportion (84/284) of AIS A SCI subjects. While

190   this study has value for demonstrating validity and providing normative data, the WISCI II was not

191   designed for AIS A subjects, as it was developed for subjects "who can stand and walk".

192

193   *Cultural issues*

194   Cultural differences are an important consideration in planning a clinical trial and our group has

195   shown differences across cultures for both clinical approaches to walking training, and consumer

196   preferences for walking with SCI.[25,36] For example, parallel bars are used far more frequently in Europe

197   than the USA,[22] which reflects the therapists' preference for equipment. This would change WISCI II

198   baseline scores if this equipment was unavailable or at least not tried. In the context of an international

199   trial, however, the effects of cultural differences are not limited to the types of walking aids and braces

200   used, but also result from differences in methods/intensities of therapy and dissimilar lengths of stay,

201   which may affect maximum WISCI II scores. Future multi-center studies across cultures (USA, Europe,

202   Asia) must consider this in the design and protocol.

203 *Braces*

204   The "grouping" of both short and long leg braces into one category "braces"[3] and the variety of

205 alternatives to short leg braces such as "alpine boots"[30] has been raised as a problem when assigning

206 WISCI II levels.

207   Our prospective study[22] showed that the "descriptors" for the different types of braces (short leg;

208 long leg, unilateral, bilateral), as listed in prior WISCI II publications[1,2] and updated on the website,[14,17]

209 may be used to record the types of braces used as subjects progress to their maximum WISCI II Level.

210 The information on the type of brace does not alter the scoring of the WISCI II level. However, recording

211 the use of aids is extremely important information in the design of a trial, because of potential cultural

212 differences. Thus the use of descriptors is recommended in planning cross cultural trials (Appendix 1 –

213 WISCI II Guide: Instructions for Use).

214   This study revealed that the use of one (9%) or two (5%) long leg braces is far less common than

215 the use of short leg braces (28%).[22] Therefore, adding separate WISCI II levels to reflect all the possible

216 brace combinations would result in a large increase in the number of levels, and does not seem warranted.

217   The criticism[3] that advance reciprocating gait orthosis (ARGO) braces are not included needs

218 clarification. ARGO braces and other devices enable subjects with complete injuries to ambulate with a

219 spring loaded assist. Such mechanical devices could impact the correlation between an underlying motor

220 impairment and demonstrated walking capacity, and were never intended to be part of the WISCI II

221 assessment of SCI subjects who can "stand and walk".

222   The descriptors (Appendix 1: WISCI II Guide: Instructions for Use) mentioned above are rarely

223 reported by those who study and utilize the WISCI II other than the WISCI/WISCI II authors

224 themselves.[22] Based on these reports, several modifications of protocol language regarding walkers and

225 braces have been adopted[14] since the original publication. Some of the web site descriptions[15,16] of the

226 WISCI/WISCI II do not make mention of the expanded list of descriptors.

227

228 *Physical Assistance*

229   For the WISCI II levels that incorporate physical assistance, there is the potential for variability in

230 the extent of assistance provided. To provide additional clarification, the descriptors for specific amounts

231 of physical assistance have been provided on the WISCI II scoring sheet. Descriptors A1 (Max Assist x 2

232 people) and A2 (Min/Mod assist x 2 people) apply only to WISCI II levels 1 and 2, both of which require

233 maximal assistance. Descriptor A3 (Min/Mod assist x 1 person) applies to WISCI levels 3, 4, 6, 7, 8, 10,

234 11, 14 and 17. The Instructions for Use also clarify that any physical contact with the subject, including

235 "contact guarding" is considered physical assistance.

236

237 *Use in Children*

238   Although two of the web sites[15, 16] are kept current and can be updated through communication

239 with the authors of the sites, there are several omissions/ inaccuracies, which have not been previously

240 addressed by the WISCI/WISCI II authors. The first has to do with the use of the WISCI II for children.

241 The psychometric properties (validity and reliability) of the WISCI II have not been evaluated for

242 children ages 13 to 21, as implied by Rehab Measures.[16] A study will be reported in 2012 that examines

243 reliability in children.[37]

244

245 *Qualifications of staff and time needed to administer the WISCI II*

246   Another issue relates to the time required to perform the WISCI II test, where one site[16] states "5

247 minutes" while the other[15] has "a minimal time". While this is accurate for the acute and sub-acute phases

248   of SCI, where therapists tend to know the capacity of their patients very well; recent studies in chronic

249   subjects, who were not known to their assessors,[10,11,35] describe the need for progressive testing of WISCI

250   II levels from self selected (SS) to maximum (Max), which may require fifteen minutes. Since there often

251   is a difference of 3 to 6 levels between SS and Max, testing cannot be performed in five minutes

252   (Appendix 1 – WISCI II Guide: Instructions for Use).

253   Perhaps the issue that requires the greatest emphasis is the need for trained clinicians to perform

254   the WISCI II assessments. In the acute and sub-acute phases, the therapist must determine the maximum

255   WISCI II level and this requires a clinical judgment based on experience, because the subjects/patients are

256   not capable of making a reliable judgment on what the minimum support needed for walking is as they

257   begin to recover ambulatory function. After the patient is discharged to the community and returns for

258   assessment 3 to 12 months post injury, the preferred WISCI II level is by definition self-selected. At

259   times subjects have developed habits of walking without braces and with an unstable ankle; testing by a

260   trained clinician is required to determine the appropriate maximum WISCI II level, especially to make

261   judgments on patient safety that limit the maximum WISCI II.

262

263   **4. Future Directions: Combining WISCI II with a Walking Speed Measure**

264   *Rationale*

265   In exploring the reasons for combining the WISCI II with a measure of walking speed, we briefly

266   examine the characteristics of both, to demonstrate why each complements the other. The nature and

267   limitations of the WISCI II, particularly its ceiling effect, have been discussed above. Subjects with a less

268   severe initial injury may recover to the maximum WISCI II level of 20 within the first 3 months after SCI

269   and will no longer see improvement on the WISCI II,[9, 23] therefore further improvement in walking

270   capacity requires assessing speed. Walking speed, however, has the limitation of a floor effect in clinical

271 trials, as illustrated in the SCILT trial.[38] The baseline data[38] for walking speed, measured for 50 feet in the

272 Dobkin trial, was assessed in less than 20% (20/142) of subjects; while all 142 subjects had baseline data

273 for the WISCI II (median = 1.49 and range 0-17). The walking speed for the 10 meter walk test

274 (10MWT) showed a floor effect[30] in a large sample of 917 subjects, in which only 6 subjects were able to

275 complete the 10MWT and TUG at 2 weeks, compared to 74 at one month and 136 at 3 months. The

276 "flying start" or dynamic start of the 10MWT, as reported by van Hedel,[30] requires subjects to walk a

277 minimum of 14 meters in order to assess the speed for the 10 middle meters which are timed, and very

278 few AIS C subjects are capable of this at 2 weeks. Upon examining the strengths and weaknesses of

279 walking speed measures and WISCI II, it seems logical to combine the two. Since the 10MWT can

280 demonstrate improvement in less severely paralyzed subjects at later stages of recovery when there is

281 often a ceiling for the WISCI II (level 20), and the WISCI II has far less of a floor effect at baseline

282 assessment, the two tests complement each other. This idea is shared in the literature,[7,8,39] and an

283 international consensus conference on ambulation and gait[6] recommended use of both measures in clinical

284 trials. Our systematic search of the literature reveals that a combination of the two measures is used not

285 only in clinical trials[40] and case series,[4,31] but has been used to validate other measures.[33]

286

287 *Is it possible to administer both tests at the same time?*

288   If it is recommended to acquire the data at the same time (i.e. during the same observed/timed10

289 meter walk), the use of a dynamic start is not possible for standardized WISCI II testing. While some

290 authors[41] recommend a dynamic start with 2 meters of acceleration before measurement of walking speed,

291 others[42] state that the static start with no acceleration is adequate. In a systematic review of walking

292 speed research in neurological diseases[42] it was concluded that the static start is the preferred method for

293 the 10MWT. In addition, Scivoletto[43] has shown that in chronic incomplete SCI patients, walking speed

294 with a static start does not differ significantly (P = 0.092) from walking with a dynamic start. Subjects

295 with the highest scores (WISCI II 18 – 20) and the lowest scores (WISCI II 9 – 12) showed no statistical

296 difference between the two methods and inter/intra rater reliability was .98-.99. Furthermore, Marino,[10]

297 Kim,[35] and Burns[11] have reported excellent correlations of walking speed measured using a static start

298 with WISCI II levels. Based on these recent studies, it appears that WISCI II and 10MWT may be

299 performed simultaneously, but this will need to be investigated in larger populations.

300
301 *Is a combined scoring system for WISCI II and 10MWT possible?*

302   A single score that encompasses the two most important agreed-upon elements of walking

303 capacity has tremendous research potential. The statistical method of blending the two metrics would be

304 the most challenging issue.

305   A recent study of walking function reported by Musselman et al.[33] attempted to validate a new

306 measure which combines timed activities, use of devices and physical assistance into one metric. The

307 authors employed both the 10MWT and the WISCI II to validate their instrument, which has many

308 similarities to a combined 10MWT/WISCI II. The ordering of assistance, which combines walking aids

309 (walkers, crutches and canes) and physical assistance from one person, however, does not take into

310 account braces. It "encompasses the timed performance of 7 tasks, such as walking and negotiating

311 obstacles, doors, and stairs." (p. 285), but not the walking capacity measured by the WISCI II or 10MWT,

312 and may serve as a complement to these measures in a trial. However, the combining of the WISCI II and

313 the 10MWT with timed activities would produce so many combinations and permutations that it is not

314 feasible.

315

316

CONCLUSION

317

318　　　The increased use of the WISCI II may be attributed to its unique characteristics as a capacity

319 measure of walking function, its strong metric properties, and recommendations by international

320 panels.[5,6,39] A systematic review of the literature found over 150 WISCI/WISCI II citations, including

321 clinical trials, cohort studies, case series, case reports, reviews and websites describing outcome measures.

322 Recent studies using the WISCI II have addressed concerns regarding the reliability of data resulting from

323 testing in chronic SCI subjects, where more time and experience by the assessor is required.

324 Misunderstandings and inappropriate use of the WISCI II scale revealed in this review of the literature

325 have required clarification and updating of the testing guide,[17] which is published as an Appendix and will

326 be disseminated electronically. The major future challenge is enhancing the utility of the WISCI II by

327 combining it with a walking speed measure, in a statistically valid way.

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CONFLICT OF INTEREST

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449   APPENDIX 1

Walking Index for Spinal Cord Injury II (WISCI II) Guide: Instructions for Use

Purpose

The WISCI/WISCI II **scale** was developed **as a research tool in clinical trials** to measure improvements in walking in persons with acute and chronic spinal cord injury.

NOTE: In a recent review of the literature (2012), it was found that clinicians have misused the WISCI II scale by documenting WISCI II levels on patients clinically, to show a more accurate snapshot of a patient's walking ability. The scale was not validated for this purpose. However, if clinicians choose to assign a WISCI II level to a patient in a clinical setting, they should clearly state whether the level is baseline/self-selected or maximum (see below).

Subject Selection

The following outline describes subjects for whom the scale is most commonly utilized:

1. Spinal cord injury subjects who are capable of standing and walking in parallel bars will be eligible for assessment. Only a reciprocal gait (without the use of mechanical device ie ARGO) is to be considered in scoring the WISCI II. Additional inclusion/exclusion criteria may be necessary.
2. Most often ASIA Impairment Scale (AIS) grade A below T10 and AIS B, C, and D subjects qualify (Ditunno 2004). AIS A subjects with a higher injury level may be included in studies that use the WISCI II but typically they would function on initial assessment at the 0 level.
3. Individuals with tetraplegia generally require motor strength in triceps of at least grade 3 or better to be able to support their body weight[3,4]. (Ditunno 2004, Dobkin 2003). Individuals with tetraplegia and arm strength in triceps of less than grade 3 may not be easily classified by the WISCI II scale (Ditunno, 2005).
4. The WISCI II has not been assessed for validity and reliability in subjects under age 18.

Standardized Physical Environment and Distance

The WISCI II is a functional capacity scale, NOT a disability scale. It must be used in a standardized environment with standardized equipment and methods, which are observed and recorded by professionals that are trained in the use of the WISCI II. The following are necessary:

1. A flat, smooth, non-slippery surface of 10 meters length.
2. Individuals walk at their own speed.

Standardized Physical Assistance

1. Any physical contact with the subject, including "contact guarding" is considered physical assistance.
2. Supervision without actual touching should not be regarded as physical assistance.
3. For additional clarification, descriptors of specific levels of physical assistance are provided on the WISCI II scoring sheet.

Standardized Equipment

1. Walkers should be conventional, but if a rolling walker is used, it should be coded as a walker and identified in the descriptors. A rolling walker has commonly been used in the USA and several European centers.
2. A platform walker is equivalent to a walker.
3. ARGOs and other mechanical devices (e.g. use of treadmills) should be excluded.
4. Crutches can be Lofstrand (Canadian) or axillary.
5. "Braces" means one or two braces, either long or short, and should be identified in the descriptors. Other devices used for bracing such as ace wraps or splints should be coded as a brace and described under "other". Equivalents of short leg braces may include high top "sneakers"; alpine shoes, or other footwear that stabilizes the ankle.
6. Whether long leg braces are locked or unlocked at the knees should be identified in the descriptors.
7. Clothing should not cover braces to allow therapists and other professional staff to make a visual determination that the patient has a brace (Ditunno, 2005).

Standardized Method

WISCI II testing is performed by physical therapists trained in the use of the WISCI II, and baseline and maximum levels are determined according to a specific protocol.

In the acute (hospital) setting, the initial (baseline) WISCI II level (i.e., the first one determined after injury onset) is determined by the therapist alone, since the patient is newly injured and must be instructed in achieving the maximum level that is safe in the hospital setting under the supervision of the therapist

In follow-up assessments after the patient has been discharged to a community setting, the following steps are required to determine the maximum WISCI II level.

Standardized Method cont.

First, the therapist interviews the subject to determine the self-selected WISCI II level, which is defined as the level the subject is ambulating at in the community, or in the household if the subject is not a community ambulator. The therapist confirms that the participant can ambulate 10 meters at the reported level. This is the self-selected level, but may not be the maximum level.

To determine the maximum WISCI II level, the therapist advances the subject sequentially through WISCI II levels starting at the level one step above the self-selected level, until the subject fails a level or is deemed unsafe for the next level. If the therapist thinks the subject can ambulate three or more levels above the self-selected WISCI II level, then to avoid fatigue, the subject can skip to a higher level. However, if the subject fails to complete that level, the subject is tested at the first skipped level and advanced until failure. If the level tested requires a brace, an alternative method of ankle stabilization as described under standardized equipment is acceptable.

Scoring

In scoring the WISCI II, first check the descriptors that apply to the current walking performance, and then assign the level of walking performance (see pgs. 7-8). For example, a subject who walks with a rolling walker and assistance of one person and no braces would be scored at a WISCI II Level 8. In selecting a level, one should choose the level at which the patient is safe as judged by the therapist, with patient's comfort level described. If devices other than those stated in the standard definitions are used, they should be documented in the comment section. If there is a discrepancy between two observers (that is, one judges the patient to be safe, the other unsafe; there never should be disagreement as to whether the patient is or is not using particular equipment; the patient's comfort level is not of relevance in assigning scores, unless insofar it informs on safety), the higher level should be chosen.

Time to Administer

The time needed to administer the WISCI II may vary from 5 minutes in the acute phase to 15 minutes in a follow-up assessment. The duration of the assessment depends on the subject's self-selected WISCI II level in the follow-up or chronic phase. For example, a subject who's self-selected WISCI II is 19 may only take 5 minutes because he/she only needs to be tested at 1 more level to reach his/her maximum WISCI II level. Similarly, a subject whose self-selected WISCI II is at the lower end of the scale may not be able to progress to a higher level and the self-selected WISCI II and maximum WISCI II levels are the same. Testing time for these two scenarios would be minimal. However, those subjects who can progress through multiple WISCI II levels beyond their self-selected level or require donning of additional

equipment (such as braces), may take longer.

Additional Notes

In clinical trials initiated in the acute phase, the increase in score is calculated by subtracting the baseline level at the beginning of the trial from the maximum level at the end of the trial.

In performing the WISICI II, individuals walk at their own speed and the 10 meters should not be timed, unless the walking speed and the WISCI II assessments are combined (Scivoletto 2011).

The WISCI II's ranking of walking levels reflecting impairment should not be dichotomized into dependent and independent levels of physical assistance, in an attempt to more closely mirror a disability scale.

Descriptors may have value in reflecting cultural differences when planning a trial.

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Research
Face Validity

Twenty-four spinal cord injury (SCI) experts in walking function from eight counties established and agreed on hierarchial ranking of 20 items. (Ditunno et al., 2000)

Results   Kendall coefficient of concordance for the pilot data was significant (W=0.843, P< 0.001) indicating agreement among the experts in rank ordering of original items

Concurrent/
Predictive/
Construct Validity

First use of WISCI II in a clinical trial of Body-Weight Supported Treadmill Training versus overground mobility training. Prospective study of 146 subjects with incomplete SCI (C4 to L3) confirmed concurrent validity of the WISCI by correlating with all measures at 3, 6, and 12 months. (FIM, 50-foot walking speed, 6-minute walk, LEMS, Berg Balance, FIM Locomotor Score). Correlation of LEMS change scores supports predictive validity (Ditunno et al., 2007).

Results - Correlations with WISCI at 6 months were significant with BBS ($r =$ .90), LEMS ($r = $.85), LFIM ($r = $.89), FIM ($r = $.77), 50FW-S ($r = $.85), and 6MW-D ($r = $.79); similar correlations occurred at 3 and 12 months. Correlations of change scores from baseline WISCI were significant for change scores from baseline of LEMS/BBS/LFIM. Correlation of baseline LEMS and WISCI at 12 months were most significant ($r = $.73). The $R2$ of baseline LEMS explained

57% of variability of WISCI levels at 3 months.

Content/Construct Validity

Prospective study of 170 subjects in four countries confirmed that progression through the levels followed a monotonic pattern in more than 80% of subjects and the relationship of walking capacity (WISCI) to impairment (LEMS) was 91% (p< 0.001) at final assessment, supporting content and construct validity. (Ditunno et al., 2008).

Results Eighty-five percent of motor complete (66/78) and 10% (7/72) of motor incomplete participants showed no progression (73/150). Of the remaining participants (77/150) who improved, 81% (62/77) showed MDI. However, the deviation from MDI occurred only at one timepoint in 10/15 participants. LEMS correlated with WISCI at initial and final assessment (0.47 and 0.91 P<0.001). Parallel bar use differed between the US and Europe possibly due to patterns of care. Use of braces also differed.

Convergent Validity/ Reproducibility

Prospective study of 76 subjects with chronic SCI confirmed convergent validity by correlating WISCI II levels to LEMS and walking speed. Reproducibility was assessed with the intraclass correlation coefficient (ICC) and the smallest real difference (SRD). (Burns et al., 2011)

Results Convergent validity of the self-selected and maximum WISCI II with LEMS was moderate for paraplegia (r = 0.479 and r = 0.533) and strong for tetraplegia (r = 0.852 and r = 0.816). Tetraplegia, but not paraplegia, demonstrated convergent validity of walking speed at the self-selected and maximum WISCI levels with LEMS (r = 0.752 and r = 0.813). WISCI reproducibility was excellent (Intraclass correlation (ICC) for self-selected level 0.995). The resulting significant real differences (SRDs) of 0.785 (self-selected) and 0.597 (maximum), suggest that a change of one WISCI level can be interpreted as real (meaningful) in a chronic patient.

Inter/Intra-rater Reliability

Study of 26 subjects with chronic SCI from the United States and Italy tested by two blinded raters on two separate days to determine self-selected and maximum WISCI II levels and the time to complete a 10-m walk confirmed inter.intra-rater reliability (Marino et al., 2010).

Results Inter-and intra-rater reliability were 1.00 for self selected WISCI. The intra-rater reliability for maximal level WISCI was 1.0; inter-rater reliability was .98. The progression from self selected to maximal WISCI level also showed high agreement between and within raters, with no communication between therapists.

Walking Index for Spinal Cord Injury (WISCI II) Descriptors

Physical Limitation for walking secondary to impairment is defined at the person level and indicates the ability of a person to walk after spinal cord injury. The development of this assessment index required a rank ordering along a dimension of impairment, from the level of most severe impairment (0) to least severe impairment (20) based on the use of devices, braces and physical assistance of one or more persons. The order of the levels suggests each successive level is a less impaired level than the former. The ranking of severity is based on the severity or the impairment and not on functional independence in the environment. The following definitions standardize the terms used in each item:

Physical assistance: 'Physical assistance of two persons' is moderate to maximum assistance.
                         'Physical assistance of one person' is minimal to moderate assistance.
                         'Contact guarding' is minimal assistance

Braces: 'Braces' means one or two braces, either short or long leg.
                         (Splinting of lower extremities for standing is considered long leg bracing).
                         'No braces' means no braces on either leg.

Walker: 'Walker' is a conventional rigid walker without wheels.

Crutches: 'Crutches' can be Lofstrand (Canadian) or axillary.

Cane: 'Cane' is a conventional straight cane.

Level   Description
0   Unable to stand and/or participate in assisted walking.
1   Ambulates in parallel bars, with braces and physical assistance of two persons, but less than 10 meters
2   Ambulates in parallel bars, with braces and physical assistance of two persons, 10 meters.
3   Ambulates in parallel bars, with braces and physical assistance of one person, 10 meters.
4   Ambulates in parallel bars, no braces and physical assistance of one person, 10 meters
5   Ambulates in parallel bars, with no braces and no physical assistance, 10 meters.
6   Ambulates with walker, with braces and physical assistance of one person, 10 meters.
7   Ambulates with two crutches, with braces and physical assistance of one person, 10 meters.
8   Ambulates with walker, no braces and physical assistance of one person, 10 meters.
9   Ambulates with walker, with braces and no physical assistance, 10 meters.
10   Ambulates with one cane/crutch, with braces and physical assistance of one person, 10 meters.
11   Ambulates with two crutches, no braces and physical assistance of one person, 10 meters.
12   Ambulates with two crutches, with braces and no physical assistance, 10 meters.
13   Ambulates with walker, no braces and no physical assistance, 10 meters.
14   Ambulates with one cane/crutch, no braces and physical assistance of one person, 10 meters.
15   Ambulates with one cane/crutch, with braces and no physical assistance, 10 meters.
16   Ambulates with two crutches, no braces and no physical assistance, 10 meters.
17   Ambulates with no devices, no braces and physical assistance of one person, 10 meters.
18   Ambulates with no devices, with braces and no physical assistance, 10 meters.
19   Ambulates with one cane/crutch, no braces and no physical assistance, 10 meters.
20   Ambulates with no devices, no braces and no physical assistance, 10 meters.

Scoring Sheet for the Walking Index for Spinal Cord Injury II (WISCI II)

Name_____   Date_____

Check descriptors that apply to current walking performance, and then assign the highest level of walking performance. (In scoring a level, one should choose the level at which the patient is safe as judged by the therapist, with patient's comfort level described. If devices other than those stated in the standard definitions are used, they should be documented as descriptors. If there is a discrepancy between two observers, the higher level should be chosen.)

Descriptors: Make ONE selection only in each section

Devices		Comments	Braces		Comments
D1 Parallel bars < 10 meters			B1 Long Leg Braces - Uses 2 – Locked at knee		
D2 Parallel bars 10+ meters			B2 Long Leg Braces - Uses 1 - Locked at knee		
D3 Walker - Standard			B3 Short Leg Braces - Uses 2 – Unlocked		
D4 Walker - rolling platform			B4 Short Leg Braces - Uses 1 – Unlocked		
D5 Walker – other > describe >>>			B5 Alpine boots		
D6 Crutches - Uses 2			B6 Ace bandages		
D7 Crutches - Uses 1			B7 High tops		
D8 Canes- Quad - Uses 2			B8 Other braces / bracing methods > describe >		
D9 Canes- Quad - Uses 1			B9 No braces		
D10 No devices					

Assistance		Comments	Patient reported comfort level		Comments
A1 Max assist x 2 people*			C1 Very comfortable		
A2 Min/Mod assist x 2 people*			C2 Slightly comfortable		
A3 Min/Mod assist x 1 person[t]			C3 Neither comfortable nor uncomfortable		
A4 No assistance			C4 Slightly uncomfortable		

Patient safety comments	

*Applies only to WISCI II levels 1 and 2; [t]Applies to WISCI II levels 3,4,6,7,8,10,11,14,17

WISCI Levels

Level	Devices	Braces	Assistance	Distance
0				Unable
1	Parallel bars	Braces	2 persons	Less than 10 meters
2	Parallel bars	Braces	2 persons	10 meters
3	Parallel bars	Braces	1 person	10 meters
4	Parallel bars	No braces	1 person	10 meters
5	Parallel bars	Braces	No assistance	10 meters
6	Walker	Braces	1 person	10 meters
7	Two crutches	Braces	1 person	10 meters
8	Walker	No braces	1 person	10 meters
9	Walker	Braces	No assistance	10 meters
10	One cane/crutch	Braces	1 person	10 meters
11	Two crutches	No braces	1 person	10 meters
12	Two crutches	Braces	No assistance	10 meters
13	Walker	No braces	No assistance	10 meters
14	One cane/crutch	No braces	1 person	10 meters
15	One cane/crutch	Braces	No assistance	10 meters
16	Two crutches	No braces	No assistance	10 meters
17	No devices	No braces	1 person	10 meters
18	No devices	Braces	No assistance	10 meters
19	One cane/crutch	No braces	No assistance	10 meters
20	No devices	No braces	No assistance	10 meters

Baseline/Self-Selected Level assigned_____

Maximum WISCI Level assigned_____