# **REVIEW ARTICLE**

The Functional Independence Measures (FIM) reliability, validity and responsiveness in spinal cord injury: literature review

Reprodutibilidade, validade e responsividade da escala de Medida de Independência Funcional (MIF) na lesão medular: revisão da literatura

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#### ABSTRACT

The Functional Independence Measures scale is one of the most frequently used tools for the assessment of functional capacity of individuals with spinal cord injuries. Measurements of the functional outcome in these individuals are essential in the rehabilitation process. This study aimed at reviewing the scientific literature regarding the reliability, validity and responsiveness of FIM in individuals with spinal cord injuries. The results showed good internal consistence, inter-rater reliability, validity and responsiveness, except for the assessment of the cognitive dimension and the locomotor domain.

#### **KEYWORDS**

spinal cord injuries /rehabilitation, disability evaluation, review literature as topic

#### RESUMO

A escala de Medida de Independência Funcional é um dos instrumentos mais utilizados na avaliação da capacidade funcional dos indivíduos com lesão medular. O registro da evolução funcional desses indivíduos é fundamental no processo de reabilitação. Este estudo teve como objetivo revisar na literatura científica a reprodutibilidade, validade e responsividade dessa escala em indivíduos com lesão medular. Os resultados encontrados mostraram alta concordância interna e reprodutibilidade inter-avaliador; validade e responsividade, exceto para avaliação da dimensão cognitiva e do domínio locomoção.

#### PALAVRAS\_CHAVE

traumatismos da medula espinhal/reabilitação, avaliação da deficiência, literatura de revisão como assunto

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# INTRODUCTION

The spinal cord injury is a disabling condition caused by trauma or disease that affects the motor, sensitive and autonomic functions.<sup>1</sup> It has an incidence of 15 to 40 cases in a million, resulting in 11 thousand new cases a year in the Unites States alone, with a prevalence of 250 thousand individuals.<sup>2</sup>

The functional impairment caused by the spinal cord injury depends on the extension and severity of the lesion<sup>3</sup> and interferes directly on the individual's capacity to perform the activities of daily living (ADL).

The assessment of the degree of functional impairment is defined as any systematic attempt to objectively measure the level of functionality in several aspects that include physical health, self management capacity, activity performance quality, intellectual status, social activity and emotional status.<sup>4</sup>

In 1983, Granger and cols, supported by the Congress and by the American Academy of Medicine and Rehabilitation, collected a set of data to measure disability and to evaluate the outcome of rehabilitation programs.<sup>5</sup> In this project, 36 tools of functional assessment, published and non-published,<sup>6</sup> were revised with the objective of identifying the most common and useful items for the construction of a scale that could assess function under several conditions of disability, such as the cerebrovascular accident,<sup>7-9</sup> multiple sclerosis,<sup>7-9</sup> spinal cord injury,<sup>10</sup> in addition to other diseases.<sup>5,9,11,12</sup> Thus, the Functional Independence Measure (FIM) appeared, a multidisciplinary tool that consisted of a set of items, with fast and uniform use, as well as consistent and reliable measures.<sup>13</sup>

In 1984, pilot studies of the FIM scale were started and at the end of the experimental phase, the current tool was attained, with 18 items. These items evaluate self-care activities (eating, getting ready, washing oneself, dressing the upper part of the trunk, dressing the lower part of the trunk and grooming); transferences or mobility (bed/ chair/wheelchair, toilet, bathtub/shower); locomotion (wheelchair/gait and stairs); sphincter control (bladder and intestine); communication (comprehension and expression) and social cognition (social interaction, problem solving and memory). Each one of these activities receives a score that goes from 1 (total dependence) to 7 (complete independence), with a total score that ranges from 18 to 126.<sup>13</sup>

The first studies on the psychometric properties of the FIM were performed when it was still under construction and were carried out in populations with different degrees of disability, including individuals with spinal cord injury. However, the results have shown to be controversial in the latter group. On the other hand, to evaluate the functional potential and record the evolution of individuals with spinal cord injury throughout time, using a reliable tool, is essential for the rehabilitation process.<sup>14</sup> The adequate measurement of functional independence in these patients implies in the capacity to classify the individuals according to the injury level (validity), present the same outcome when evaluated by different examiners (reproducibility) and identify changes throughout time (responsiveness).

Therefore, the aim of the present study is to revise in the scientific literature the reproducibility, validity and responsiveness of the FIM scale in the assessment of individuals with spinal cord injury.

## METHOD

The literature search was carried out using the following databases: MedLine Pubmed with the key words Reproducibility of Results or Validation Studies, Spinal Cord Injuries and Disability Evaluation available at MeSH and at the Lilacs database, with the key words *Validacao* (Validation) and *Reabilitacao* (Rehabilitation), obtained from the Key Words in Health Sciences– DeCS of Bireme database. The studies published up to June 2007 and their references were selected, with no lower date limit, including only those that evaluated the properties of the FIM scale in individuals with spinal cord injury and excluding those that did treat separately the data concerning this population.

# RESULTS

A total of 16 studies were found. The data concerning the design, statistical analysis and results (reproducibility, validity and responsiveness) were organized by date of publication of the articles (Table 1) and the review results were grouped by psychometric properties. Most of the studies evaluated the properties of the FIM scale items, separating motor and cognitive dimensions.<sup>6,10,12,15-18</sup>

## I Reproducibility

The reproducibility evaluates how much an instrument is free of random error or provides a reproducible outcome, i.e., the same result in repeated measures. The reproducibility of a tool is quantified when it is submitted to similar circumstances through the test-retest and is divided in intra and inter-observer.<sup>19,20</sup> The first refers to the consistency of the findings after several assessments made by the same observer<sup>20</sup> and the second measures the degree with which two or more individuals agree between them.<sup>20</sup>

The inter-observer reproducibility was high in individuals with different types of disability.<sup>21,22</sup> Regarding the spinal cord injury, only one study evaluated the inter-observer reproducibility of the FIM scale, and found good a correlation rate.<sup>1</sup>

The intra-observer reproducibility was not found in the studies, but as it is a generic tool, maybe the results observed in other populations can be extrapolated to individuals with spinal cord injury.

Three test-retest studies were found, which presented different objective and methodology and could not be compared.<sup>23-25</sup>

One of the studies compared the use of the scale through the observation of task performance (as specified by the FIM scale) and through a questionnaire directed at the patient and his/her caregiver, which is known as equivalent reproducibility. No significant difference was observed between the two forms of tool use, but the use of the questionnaire is advantageous, as it takes less time (on average 7 minutes and a half; SD = 3.63) than the observational evaluation (on average 1 hour, SD = 25.36).<sup>24</sup> This study is important for clinical practice, as the FIM is applied not only to the inpatients, but also to the outpatients, where patient and caregiver are questioned regarding the activities of daily living developed in the house. No studies were found in which the FIM scale was used as a questionnaire to evaluate the interobserver reproducibility.

The scale reproducibility was also evaluated when applied by the patient him/herself and when applied by a trained professional. Good reproducibility was observed in the total score and by items, except in the cognitive dimension. This study did not describe the statistical method used and carried out the assessments with a month interval between them, i.e., comparing the scores of the two types of scale use at different moments.<sup>25</sup>

Another concept related to reproducibility is the internal consistency, which measures to which extension a test or tool evaluates

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Table 1
Description of the studies on the reproducibility, validity and responsiveness of the Functional Independence Measure (FIM) scale.

AUTHOR/YEAR	SAMPLE	STATISTICAL ANALYSIS		RESULTS	
			REPRODUCIBILITY	VALIDITY	RESPONSIVENESS
Davidoff GN and cols. <sup>10</sup> / 1990 ‡	Case Group (SCI): N=41; L=20%   age: 30.4±1.7; men: Control Group (w/t SCI):   855%; level of schooling: N=22; age: 27.7±2.0; men   12.9±0.4 years; lesion 55%; level of schooling:   level: C=41%, T=39% 13±0.2 yrs	Scatter Plots : Mean and SD		Cognitive score: ceiling effect.	-
Dodds TA and	Evaluation at hospital admission and release;	Cronbach's $\alpha$	Low internal consistency in locomotion item	Good construct validity	Responsive.
cols.27/1993 *†	N=786 patients registered at UDSMR	T Test	(0.41).		
Segal ME	N= 57 patients	Pearson's Coefficient of	High concordance (0.74-0.87) for complete		Responsive, except for the cognitive
and cols.23/1993*†		correlation T Test	lesions and incomplete paraplegia; low concor- dance for incomplete tetraplegia (0.49).		domain.
Marino RJ and	N=22 men with lesions from C4-C7 up to 72h of SCI;	Spearman's Coefficient		FIM and EMMS: good correlation (0.84).	-
cols32/1993*†	age: 18-63	of correlation		FIM and QIF: very good correlation (0.93).	
Grey BA and	N=40; men: 85%; paraplegic: 67.5%; age at the	Unspecified Coefficient	Total score (0.83);	-	-
cols <sup>25</sup> / 1993*	moment of the SCI: 29.6 (SD=9.57); mean time	of correlation	per domains (>0.71);		
	between data collection of both groups: 7.25 weeks		Cognitive dimension (<0.45).		
	(SD=1.93)				
Stineman MG and	N=4440 individuals with traumatic (1831) and non-	Cronbach's $\alpha$	Good internal consistency:	Stairs: floor effect	-
cols.12/1996*	traumatic (2609) SCI registered at UDSMR		total, motor, cognitive FIM		
		Factorial analysis	Low correlation (<0.42): stairs, comprehension,		
			expression and memory.		
			Good correlation: bathing, dressing LLLL,		
			bathroom and transferences.		
OtaT and cols. <sup>30</sup>	N= 100 paraplegic and tetraplegic patients; Frankel	Comparison of scores		Validity among tetraplegic and paraplegic individu-	Ceiling effect:
/1996*†	A and B;	without statistical		als. No validity among paraplegic individuals $>$	tetraplegics: 10 months.
	men: 84; mean time of lesion: 29 months	analysis		T5 and <t6.< td=""><td>SCI &gt; T5: 6 months.</td></t6.<>	SCI > T5: 6 months.
					SCI < T6: 3 months.
Heinemann AW and	N=53 patients registered at UDSMR	Paired † Test	-	Educational activities and administration of	Responsive for total FIM. §
cols18/1997*†				d rugs: negative correlation between FIM and time	
		Pearson's Coefficient of		spent. Indirect activities: negative correlation only	
		correlation		at hospital release.	
Karamehmetoglu SS	N=38 patients; men: 76%; age: 33.94 ±1.59;	Spearman's Coefficient	Questionnaire versus performatic: good respon-		-
and col <sup>24</sup> /1997*	paraplegics: 78%	of correlation	siveness. Higher correlations: comprehension	-	
			and memory.		
			Lower correlation: LLLL dressing.		
Stineman MG and	N=84537 patients registered at UDSMR	Cronbach's $\alpha$	Good correlation:		-
col.15/1997*			Total, motor and cognitive FIM.		
		Factorial analysis	Traumatic SCI: activities related to UULL, LLLL		
			and cognitive.		
			Non-traumatic SCI: self-care, sphincter, mobility,		
			cognitive.		

N: Number of individuals; SCI: spinal cord injury; C: cervical; T: thoracic; L: lumbar; UDSMR: Uniform Data System for Medical Rehabilitation; FIM: Functional Independence Measure; ULMS: upper limb motor score. QIF: quadriplegia index of function; UUL: upper limbs and LLLL lower limbs; SD: standard deviation. \* Transversal study; † longitudinal study; ‡ case-control study; § Evaluation at hospital admission and hospital release; Does not apply

the same characteristics, capacities and qualities.20

The items that are considered redundant at the internal consistency evaluation must be grouped. This measure is carried out through Cronbach's  $\alpha$ , which, when >0.7, reflects a good internal consistency.<sup>26</sup> The articles found in the literature search showed good internal consistency in the motor and cognitive dimensions and in the total FIM score.<sup>12,15</sup>

Other models for the grouping of items from the FIM score (conceptual models) were proposed and organized with the objective of exploring certain domains, of which validity of content is evaluated by a group of specialists with clinical experience and who are involved in research.<sup>19</sup> At the evaluation of the consistency of these models, a low correlation was observed between the items: LLLL dressing,<sup>24</sup> stairs, comprehension, expression and memory<sup>12</sup> and locomotion,<sup>27</sup> which varied among the studies and depended on the level and severity of the lesion<sup>23</sup> and the type of lesion (traumatic or non-traumatic).<sup>15</sup>

The clinical usefulness of these divisions is the possibility of detecting functional changes that can occur in a set of items and not in others. For instance, individuals who are independent in self-care, but dependent in mobility receive the same motor score than those

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Description of the studies on the reproducibility, validity and responsiveness of the Functional Independence Measure (FIM) scale.

AUTHOR/VEAR	DESIGN	STATISTICAL ANALYSIS	RESULTS			
A BIHON PLAN			REPRODUCIBILITY	VALIDITY	RESPONSIVENESS	
Middleton JW and cols.17/1998*	N=167	ANOVA	-	Cognitive score: no difference. Motor score: higher at more	-	
	C1-C4, N=11; C5, N= 19; C6, N=24;			caudal levels; Significant between C6 and C7-8. Self-care and sphingter management and mobility differentiates tetranlegics.		
	C7-C8, N=7;T1-6, N=13 and T7,			from paraplegics. Mobility: differentiates lesions below and abo-		
	N=38			ve T7. Locomotion: ceiling effect in gait/CR; floor effect in stairs.		
Hall KM and cols. <sup>6</sup> / 1999*	N= 3971 (admission); 4033 (hospital	Kruskal-Wallis	Good Correlation (>0.72): transfe-	-	Escore cognitivo: efeito teto.	
	release); 903 (1 yr); 714 (2 yrs);	Mann- Whitney	rences; eating and getting ready;		Escore MIF motor: Responsiva até	
	570 (5 yrs)	Unspecified Coefficient of correlation	dressing UULL and LLLL		o segundo ano.	
Riberto M and cols. <sup>16</sup> / 2004*†	N= 93 patients from HC-FMUSP	Paired non-parametric tests	-	Cognitive FIM: no difference	Responsive for total FIM and in	
	and 57 from Umarizal Rehabilitation	ANOVA		Motor FIM: higher score in lower lesions	items separately. §	
	Center; men: 72%; age: 33.8 ± 13.9;			Feeding, bathing locomotion: tetraplegic different from		
	Traumatic SCI: 78.7 %; mean time			paraplegic.		
	of lesion: 9.7 ± 13.6 months; lesion			Toilette: cervical different from lumbar.		
	level: C: 30.5%; T: 52.7%; L: 17.0%.			Sphincter management/shower transfer: lumbar differs		
				from cervical and thoracic.		
				Mobility: difference among groups.		
Morganti B and cols. <sup>1</sup> / 2005*	N=184 men and 100 women ;Age:	Spearman's Coefficient of correlation	Good intra-observer reproducibility	Locomotion domain presents good correlation (> 0.7) with	-	
	50.4 ± 19,.3 yrs Time of lesion: 56.9 ± 43.9 days Traumatic /Non-traumatic			the scales: WISCI; RMI; BI; SCIM;		
	ESION: 1777284 LEVELONE OF ESION: C.81; T:148; L/S:55 ASIA:A:84; B:19; C:129; D:52.					
/liddleton JW and cols.28/2006*†	N=39	Mann-Whitney	-	Transference: good construct validity	Transferences: responsive in	
	Age: 18-65 yrs	Friedman		Gait/CR: ceiling effect.	paraplegics and floor effect in	
	2 groups: paraplegics and			Stairs: floor effect	tetraplegics.	
	tetraplegics				Locomotion: ceiling effect.	
Lugo LH and cols. <sup>29</sup> /2007†	N=42 ; men: 88%; Age≤ 44 yrs;	Kolmogorov-Smirnov	-	FIM score increases according to lesion level and ASIA.	Responsive for motor score	
	lesion level: C = 27.8%, T1-T6 =	Mann Whitney			between admission and 1 month	
	40.9%, <t6=31.2%.< td=""><td>T Test</td><td></td><td></td><td>and between 1 month and 12</td></t6=31.2%.<>	T Test			and between 1 month and 12	
					months;	
					C: admission and 12 months;	
					T: up to 12 months;	
					Ceiling effect:	
					ASIA A/B – in 18 months;	
					ASIA C/D/E – in 12 months.	

in the opposite situation, i.e., dependent in self-care, but independent in mobility. The regrouping of the items can increase the tool responsiveness.

## **II** Validity

The validity is the property that evaluates the capacity of the tool to measure what it proposes to do. For instance, the assessment of functionality must include items such as personal care, mobility and locomotion. It must be related a particular situation, a proposal or a population in which the tool will be applied to.<sup>20</sup>

### **II.I Construct Validity**

The construct validity evaluates the degree of compliance of a tool with the theory through the associations between relevant parameters. $^{19,20}$ 

The studies that evaluated the construct validity of the FIM scale in spinal cord injury usually associated the obtained scores with the level of the lesion. It is expected that individuals with higher level lesions, with more severe involvement of the muscular strength of the upper limbs be more dependent, i.e., present lower scores than those that present a lower neurological involvement.

The comparison among studies is difficult to carry out, due to the lack of sample characterization. Additionally, the number of individuals is small and the stratification varies between: two groups (paraplegic and tetraplegic individuals);<sup>28</sup> three (cervical, thoracic and lumbar);<sup>16</sup> and four groups, based on the preserved musculature<sup>6,17,29,30</sup> or severity of lesion.<sup>27</sup> The division of a small number of patients in groups can lead to a type II error in the analysis of results (not finding a difference when there is one).

The studies demonstrated a good construct validity in the assessment of the total score<sup>16-18,27,29,30</sup> and the motor dimension,<sup>16,17</sup> showing a difference among the patients, as individuals with higher lesions presented lower scores.

At the assessment of the cognitive dimension, all studies showed low construct validity, as no significant difference was found in the score between the paraplegic and tetraplegic individuals, regardless of the lesion severity.<sup>10,16,17</sup> In this case, issues such as comprehension, expression, memory, problem-solving and social interaction are not relevant in the functional assessment, as these individuals maintain the superior brain functions intact, except when there is associated head trauma. Thus, they receive the maximum score, which characterizes the ceiling effect between the groups.

At the assessment of each item of the FIM scale, separately, most studies presented low sensitivity in the detection of differences between the groups in the locomotion domain (gait/wheelchair and stairs).<sup>12,17,28</sup> The "climb stairs" item showed a floor effect in most studies, with a score of 1,<sup>12,17,28</sup> and the gait/wheelchair item, a ceiling effect with a score of 6.<sup>17,28</sup> In this last case, paraplegic individuals in manual wheelchairs as well as tetraplegic individuals in motor wheelchairs can receive the same score, in spite of their functional differences. Regarding the stairs, most individuals with spinal cord injury use the wheelchair exclusively for locomotion, which makes them dependent for this task. Only one study carried out in Brazil found a difference regarding the locomotion item between paraplegics and tetraplegics; however, no difference was observed in the score between those that presented thoracic lesion and the ones that presented lumbar lesion.<sup>16</sup>

The difference found might be due to the difficulty that the

tetraplegic living in Brazil have of acquiring a motor wheelchair, thus receiving a lower score than the paraplegic individuals, as they present more difficulty in locomotion in a manual wheelchair.

At the assessment of the mobility, self-care and sphincter management, we observed a difference among the studies that can be attributed to the criterion adopted for the sample stratification.<sup>16,17,28</sup>

## **II.II** Concurrent Validity

The concurrent validity can be called instrumental validity or criterion-related validity. It is used to demonstrate the accuracy of a tool through the comparison with the gold-standard.<sup>15,31</sup> Two studies compared the FIM scale with other tools, presenting good correlation among them.<sup>1,31</sup> Another study evaluated the concurrent validity of the FIM scale, comparing its score with hours of nursing care required by the patients per day presenting good correlation. That is, the individuals that need more hours of care are those that present low scores.<sup>32</sup>

### **III** Responsiveness

The responsiveness is the capacity of a tool to measure changes in a pre-established period of time<sup>31</sup>. In the studies that evaluated the responsiveness of the FIM scale in spinal cord injury, the time interval between the hospital admission, hospital release and post-hospital release reassessment varied broadly and was not always described. Several studies observed a good responsiveness at the admission and the release.<sup>6,16,18,27</sup> The responsiveness at three different times: admission, release and reassessment was also good for the total score after three months6 and for the motor dimension after one<sup>29</sup> and two years<sup>16</sup>, regardless of the level and severity of the lesion. Ota et al,<sup>30</sup> in a study carried out in Japan, identified that the responsiveness varies according to the level of the injury. However, this study evaluated a small number of patients in each group and did not consider an adequate statistical test to evaluate the possibility of the occurrence of type I error. Lugo et al 29 demonstrated that individuals ASIAA and B presented a ceiling effect one year and a half after the injury, whereas individuals ASIAC, D and E reached the maximum score within one year.

A low responsiveness was observed for the items transference in tetraplegic individuals<sup>28</sup> and for the item locomotion and cognitive dimension, regardless of the level of the injury.<sup>6,28</sup>

One of the studies collected data from different samples, at three moments, which is not an adequate design for the assessment of responsiveness. The losses were considered, but the reason was not described.<sup>6</sup>

# CONCLUSION

The studies found in the search presented different results regarding the validity and the responsiveness in the assessment of the total and motor score and of the 13 motor items evaluated separately. It is interesting to observe that most of the studies were developed in English-speaking countries and only one was carried out in Brazil by Riberto et al.<sup>16</sup>

Lawton et al<sup>33</sup> stated that the differences found in the results might be due to factors such as the degree of difficulty presented by the patients when performing the tasks, which varies among populations from different countries; differences in translation, in the training given to those applying the scale and the versions used in the assessment.

Questions related to the translation and training influence the

psychometric quality of the tool, decreasing its reproducibility and making comparisons difficult. However, a quantitative review on this subject, comparing several studies with different populations, showed good equivalent reproducibility, as well as intra and interobserver reproducibility.<sup>22</sup>

The floor effect was observed in both the validity and the responsiveness assessment and the ceiling effect in some items. The observation of these effects is the result of the lack of precision and capacity of a tool to detect significant changes in the functional levels of individuals located at the extremities. If an individual has a maximum or a minimum score in one measurement, the occurrence of improvement or worsening, respectively, cannot be identified. It is important to mention that there are methodological restrictions in the data analysis, as an adequate statistical test was not always used. Many studies used parametric tests to analyze the ordinal variables, with a small sample and distribution that differs from the normal one. In these cases, the use of non-parametric tests is indicated.

In general, the literature review allowed us to verify that the FIM scale presents high internal concordance and good interobserver reproducibility. The scale presented good results regarding the validity and responsiveness.

The FIM is a generic tool, created to evaluate functional independence through its total score. Although the fragmented analysis of this tool is not formally recommended by the UDSMR, the division of the scale into motor and cognitive dimensions has been often employed in the literature. Many studies evaluated the properties of different combinations of FIM items and most of them observed low validity and responsiveness, in the locomotion domain as well as in the cognitive dimension. Individuals with spinal cord injury can present cognitive impairment, depending on the etiology of the injury or comorbidities and, but for exceptional cases, they present locomotion impairment, which is broadly variable according to the lesion characteristics. Therefore, if one wants to focus on one of these aspects, other tools must be used, as the FIM scale, although largely employed, presents low sensitivity in this context. One alternative would be to maintain the use of this scale, which is broadly used, and aggregate items that can increase its sensitivity in certain situations.

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