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Additional Information

## **“Determining cut-off points in/for functional poststroke assessment scales”**

### **INTRODUCTION**

Appropriate assessment of post-stroke patients is an important element for quality of care and is a constant recommendation in all the International Guidelines for the management of these patients. Use of a standardized assessment helps identify and quantify the degree of neurological deficits, facilitate communication between clinicians, provides outcome information, and helps treatment selection to increase effectiveness in rehabilitation. A wide variety of well-validated instruments for the assessment of functioning and disability have been developed [1-5], which enable the extent of the sequelae of a stroke, and subsequent recovery, to be determined [6].

The Barthel Index (BI), Functional Independence Measurement (FIM) and Functional Assessment Measurement (FAM) scales have been validated and globally used for functional assessment in this population. Although these scales can capture minimal changes in physical functioning, they have limitations in their application. Because these scales yield ordinal values, researchers or practitioners may have difficulties in understanding and interpreting the clinical meaning of total scores or score changes when these occur. Interpretation of each instrument's raw score is limited to numeric increases or decreases in total score. In order to provide more interpretable information on post-stroke outcomes, several assessment scales have been stratified or divided into categories, which distinguish different levels of recovery [4,5,7-9].

Several cut-off points have been suggested for the categorization of some of these instruments. The assessment scales most commonly used in order to establish such cut-off points are the BI and the Modified Rankin Scale (mRS) [2,9,10]. Less frequently, the FIM has also been used in a variety of such studies [5,11]. While the cut-off points used in the functional assessment scales such as the BI [2,9,12-16] and the FIM [11] are highly variable,

a more consistent stratification of recovery levels has been determined for the mRS [9,16].. However, mRS represents a unidimensional scale heavily weighted toward global disability (in particular physical disability), so other instruments have been developed in an effort to reflect nonphysical attributes essential to a person's self-maintenance and well-being, such as cognition, behavior and social functioning. The Differential Outcome Scale (DOS) is one of these multidimensional tools listed within the functioning and disability component of the International Classification of Functioning, Disability and Health (ICF) framework [Tate et al., 2013]. Since the use of multidimensional scales is not generalized, the categorization of outcome levels in most of these tools has not been so widely studied. In the case of the Differential Outcome Scale (DOS), such a categorization has only been performed for its four sub-scales (neurological, cognitive, behavioural and social sequelae), but not for the overall DOS [17].

To improve the clinical interpretation of functional and activities of daily living (ADL) assessment scales could be an issue of greatest clinical value. Moreover, lack of consistency in categorization of these instruments and selecting their appropriate cut-off points for defining recovery or disability levels (in respect to global disability scales) represents a major limitation in research.

The purpose of this study is to differentiate clinically distinct categories of disability for the BI, the FIM and the FAM and to determine their cut-off points. The mRS and the DOS, which have been used to define stroke disability categories, were used as reference and the relationship between these two global disability scales was analyzed.

## **MATERIALS AND METHODS**

### **Study population and study design**

Data were obtained from a large database which includes information on basic demographics, diagnoses, and patient functional status at admission to and every 6-months

until discharge from a rehabilitation program in Hospitales Nisa in Valencia (Spain). This specific program provides organized stroke rehabilitation across a continuum of care, from the acute stroke service to return to home and community life. The program usually includes acute and post-acute intensive inpatient multidisciplinary rehabilitation as well as chronic low-intensity and/or home-based therapies, combined with specific community integration programs. All patients with the diagnosis of ischemic or haemorrhagic stroke were candidates for inclusion. Patients presenting with a disorder of consciousness, including those in a vegetative or minimally conscious state according to the Coma Recovery Scale–Revised, were excluded.

All participants provided informed consent. Our study was approved by the local Institutional Review Board.

This is a cross-sectional study, in which the post-stroke assessment total scores for the BI, FIM, FAM, DOS and mRS were collated. To obtain a robust categorization scheme, data available on the patients over a one-year period (baseline, 6 and 12 months) was aggregated.

### **Assessment scales**

#### **Barthel Index (BI)**

The BI is a functional-ADL scale composed of 10 items. Two items regarding personal toilet and bathing are evaluated with a 2-score scale (0 and 5 points); 6 items regarding feeding, getting onto and off the toilet, ascending and descending stairs, dressing, controlling bowels, and controlling bladder are evaluated with a 3-score scale (0, 5, and 10 points); and 2 items regarding moving from wheelchair to bed and returning, and walking on a level surface are evaluated with a 4-score scale (0, 5, 10, and 15 points). The total BI score, which is calculated by summing each item score, oscillates between 0 (completely dependent) to 100 (independent). Higher scores represent a higher level of independence [18].

#### **Functional Independence Measures (FIM)**

The FIM was designed to assess changes in functional status in daily tasks performance. From its 18 items, 13 define disability in motor functions (eating, grooming, bathing, dressing upper body, dressing lower body, toileting, managing bladder, managing bowel, transferring to bed/chair/wheelchair, transferring to toilet, transferring to tub/shower, locomotion by walk/wheelchair, and locomotion on stairs) and five define disability in cognitive functions. Each item is rated on a 7-point scale (1\_complete assistance to perform basic ADL, 2\_maximal assistance, 3\_moderate assistance, 4\_minimal assistance, 5\_supervision, 6\_modified independence, and 7\_complete independence in performing basic ADL). The total FIM score takes values from 18 to 126 and the degree of dependency ranges from no helper to complete dependence on a helper [19].

#### FIM + FAM scale (FAM)

The FIM+FAM scale (FAM), which was specifically developed for use in brain injury, it does not stand alone, but adds a further 12 items to the FIM which specifically address cognitive and psychosocial issues, while applying the same 7-level scoring system. It has a total of 30 items and its global score goes from 30 to 210 [20,21].

#### Modified Rankin Scale (mRS)

The mRS is an outcome measure of global disability, which measures independence rather than performance of specific tasks. This scale defines 6 levels of disability and 1 for death: 0\_no symptom at all; 1\_no significant disability despite symptoms, able to carry out all usual activities; 2\_slight disability, unable to carry out all previous activities but able to look after own affairs without assistance; 3\_moderate disability, requires some help but able to walk without assistance; 4\_moderately severe disability, unable to walk without assistance and unable to attend to own bodily needs without assistance; 5\_severe disability, bedridden, incontinent, and requiring constant nursing care and attention; and 6\_dead [22,23].

Cut-off points for the categorization of the mRS have been proposed by the literature. A score of 5-6 represented severe disability, 3-4 moderate disability and 0-2 mild disability [9,16,24,25].

## Differential Outcome Scale (DOS)

This is an assessment scale that specifies outcome in four subscales on social, behavioural, cognitive, and physical sequelae. In each category of outcome a 5-score scale is applied, with values of 1-2 representing severe disability, 3-4 moderate disability, and 5 mild disability. The lowest total score attainable is 4 points for a persistent vegetative state and the highest total score is 20 points for complete recovery [17].

Therefore, although not established in the literature, cut-off scores for the overall DOS scale were obtained by averaging the cut-off scores already determined for the four subscales. Thus, an overall score of 4-10 represented severe disability, 11-17 moderate disability, and 18-20 mild disability. This cut-off points were taken as reference for the purpose of this study.

## Statistical Analyses

A contingency table was used to determine the relationship between the different disability levels determined by the DOS and mRS scales, whose cut-off points for disability levels definition have been described above. Additionally, a binary logistic regression analysis was used to establish the cut-off points for BI, FIM and FAM, based on the DOS and mRS disability levels. One binary logistic regression model for each of the six possible combinations of these assessment scales was elaborated, taking DOS or mRS as dichotomous outcome variables (achievement of a superior disability level or nonachievement) and BI, FIM and FAM as explanatory variables. Statgraphics Plus version 5.1 software was used to perform these analyses.

## RESULTS

A total of 106 subjects (45.3% women, 54.7% men) were recruited for participation in this study. The median age of the sample was 69 and most of them (85.9%) were between

65 and 75 years. Median chronicity was 82 days and 58.5% of the patients presented chronicity below 100 days. 67.9% of the sample had suffered an ischaemic stroke and 32.1% a haemorrhagic stroke. The median BI and FIM values were 23.5 and 42, respectively, and the mRS values ranged between 3 and 5, indicating a severe disability in our sample.

First of all, the relationships between the different disability levels (mild, moderate and severe) currently in use with the DOS and mRS scales were determined using a contingency table. Thus, in Table 1 a positive correlation was observed between the two ordinal scales (with a positive and highly significant Kendall's tau-b statistic), although a certain amount of disagreement between the two scales for the three disability levels was also detected.

From the results of the six binary logistic regression models, showed in Figure 1, cut-off points in the BI, FIM and FAM were determined. Given the high level of severity in our sample, meaning that practically no patient achieved a good level of recovery (mild disability), this study has only focused on the lower cut-off point. Ideal cut-off points were defined as the corresponding scores for BI, FIM and FAM that have an equal 50% probability of being located in either of two adjacent DOS and mRS disability levels (severe and moderate disability).

The lower cut-off points (with their 95% CI), separating the levels of severe and moderate disability, in the functional-ADL scales, derived from the cut-off points of the global disability scales (the DOS and the mRS respectively), were: 62.90 (57.26-69.29) and 21.30 (16.34-26.03) for the BI; 70.62 (66.65-75.22) and 38.29 (34.07-42.25) for the FIM; and 116.07 (110.30-122.68) and 66.02 (59.20-72.35) for the FAM.

## **DISCUSSION**

## Contingency table

Researchers and practitioners often rely on categorization, using disability levels or categories from global disability scales for poststroke measurement and assessment. This study showed the relationship among mRS and DOS disability levels. Although these scales were highly correlated, the discrepancies observed between the disability levels of the two global scales (Table 1) enable the two to be ranked in terms of how demanding they are, with regard to the independence required in order to be categorized as mild, moderate or severe disability. The results of this study indicate that the DOS scale is more demanding in this respect, and the mRS less so. The mRS requires a relatively low functional status in order to be considered moderate disability. This means that patients with maximal functional limitations were in a better position to be assessed using the mRS (categorized as moderate disability) as compared to DOS (categorized as severe disability).

Studies comparing how demanding the different post-stroke assessment scales are scarce. Weimar *et al.* [26] and Duncan *et al.* [2] compared recovery assessment as measured by the BI and mRS scales, while Kwon *et al.* [5] established this comparison between the mRS and both the BI and the FIM. The results reported in these investigations are somehow consistent with our findings, demonstrating that the mRS is less demanding when compared with other assessment scales (in this case, the BI and the FIM). According to Duncan *et al.* [2], this difference could be mainly due to the fact that the mRS is more subjectively evaluated thereby leading to more chances of misclassifications. To our knowledge, this is the first study that analyses the relationship between the mRS and the DOS scale.

In the case of the present study, the standard of recovery required by the scales may vary as a result of their different approaches to the assessment of poststroke status: the mRS assesses disability, providing information on the level of functional dependence or personal autonomy [23], whereas the DOS considers the problem from the point of view of



participation, also taking into account cognitive, social and neuro-behavioural factors. The fact that the DOS considers these additional factors may be the reason why it is more demanding in its assessments [5,8,17].

### **Categorization scheme**

In this study, we used the mRS and the DOS as a reference to categorize the BI, FIM and FAM scales because we are interested in developing a scheme that converts functional-ADL measures to a global disability measure that presents clinically distinct disability levels. The mRS and the DOS are appropriate as a reference for this purpose because their categories facilitate the clinical interpretation of poststroke outcomes [4,5,7-9], they give specific information concerning remaining impairments and they respond well to patient outcomes [26].

With regard to the cut-off points determined by this study, those for the FAM were higher than those for the FIM, and the latter were, in turn, higher than those calculated for the BI. However, we consider that this finding was merely a consequence of the different ranges of these three scales (0-100 for the BI, 18-126 for the FIM and 30-210 for the FAM). On the other hand, it was found that the cut-off points were in general much higher when the reference scale was the DOS, than when the reference scale was the mRS. This could be a further reflection of the difference in how demanding the two scales are in favour of the DOS compared to the mRS. In addition, this could be due to the different nature of the scales itself rather than the inferiority of these instruments.

The cut-off points proposed by the literature for the BI are highly variable. They have been ranged from  $\geq 50$  to  $\geq 95$  [2,9,12-15]. A total score of 60 has been the most commonly used BI score to identify different degrees of disability in poststroke patients [15]. This is in agreement with our findings, determining a very close cut-off point of 62.90 for the BI when taking the DOS as reference. Granger *et al.* [13] found that the BI score of 60 was a significant score to differentiate patients needing some sort of assistance (mildly

independent) and patients requiring complete assistance to perform their daily functional living activities. Nevertheless, other investigations have determined other cut-off points for the BI, which differ significantly from our results. Scores of  $\geq 90$  [27] and  $\geq 95$  [15] have been considered, indicating a favorable outcome and a lack of assistance required to perform ADL. Although Uyttenboogaart et al. [16] also found BI cut-off scores, they did it by correspondence with mRS lower categories (those indicating mild and moderate disability) as reference, which is not the case in our study, as our sample had more severe disability.

With respect to the FAM, this is, to our knowledge, the first study analysing the cutoff-points for this scale. Few studies have investigated about the cut-off points for the FIM. Inoyue *et al.* [11] used FIM cut-off points to classify patients in terms of stroke severity in the following manner: severely affected,  $FIM \leq 36$ ; moderately affected,  $FIM 37-72$ ; and mildly affected,  $FIM \geq 73$ . The lower cut-off point (the threshold between severely and moderately affected patients) does not differ greatly from that determined in this study for the FIM scale (38.29; 95% CI 34.07-42.25) being within our confidence interval. Kwon *et al.* [5] examined the relationship between the disability levels classified by the mRS with those of the BI and the FIM. This study determined the cut-off point for the FIM at 23, and at 15 for the BI. In both cases, these cut-off points are lower than those found in our study when taking the mRS as reference, being slightly below the lower limit of our confidence intervals. However, it is important to note that, although Kwon *et al.* studied the lower mRS scores in greater detail than the higher ones, as is also the case in our study (which considers only the lower cut-off point), they described specific cut-off points corresponding to scores of 3, 4 and 5 in the mRS, whereas here we have studied mRS scores of 5 and 6 together on the one hand and scores of 3 and 4 together on the other.

Moreover, other classification strategies not based on cut-off points determination from the FIM total score, have been developed in the last years. In 2003, Stineman et al. [29,30] presented a staging and grading system that categorizes the patient based on the nature of the disability state, while still measuring severity of the impairment. These systems

are based on the specific FIM subscores that rate activities in the domains of ADL, sphincter management and mobility. The Functional Independence Staging system (FIS) expresses activity limitations and participation restrictions, by estimating the average amount of effort the patient is able to provide when attempting to complete the entire set of activities in the three FIM domains [29]. Moreover, the grading system summarizes information across these motor domains as a single number. The six final grades reflect the most typical patterns of function that correspond to each physical independence value [30].

### **Study strenghts**

With regard to attempting a precise and scientific determination of the cut-off points, two different statistical approaches have been used by researchers in this field. While some researchers have employed Receiver Operator Characteristic (ROC) analysis [16,28], others have chosen logistic regression [8]. We also performed logistic regression analysis in this study, given that, as an inferential method, it enables the level of uncertainty of the cut-off point estimation to be determined.

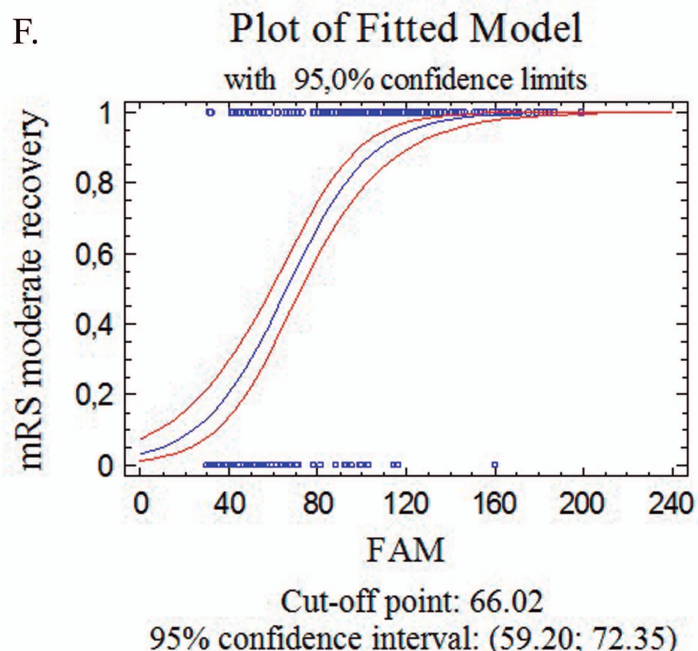
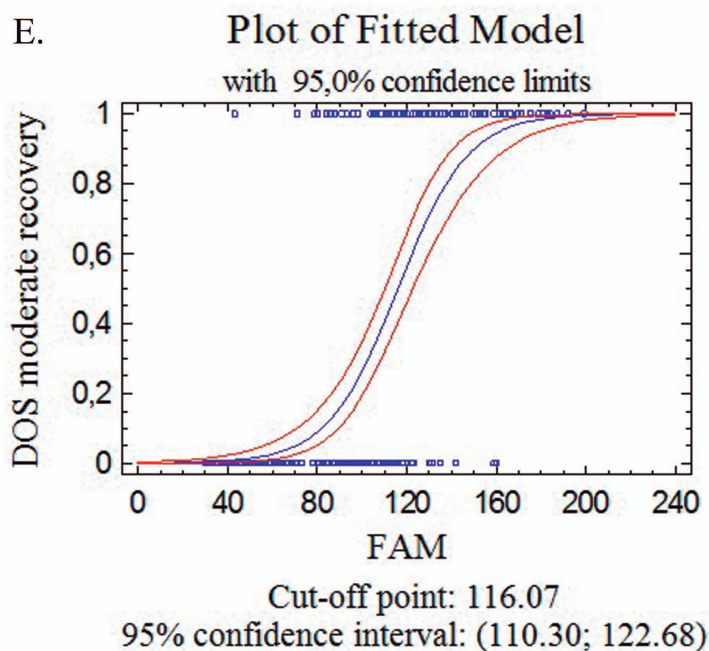
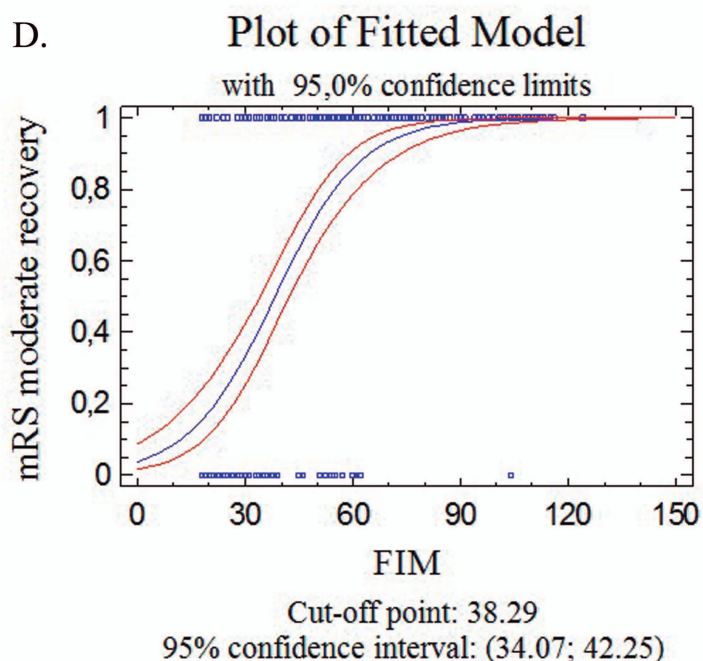
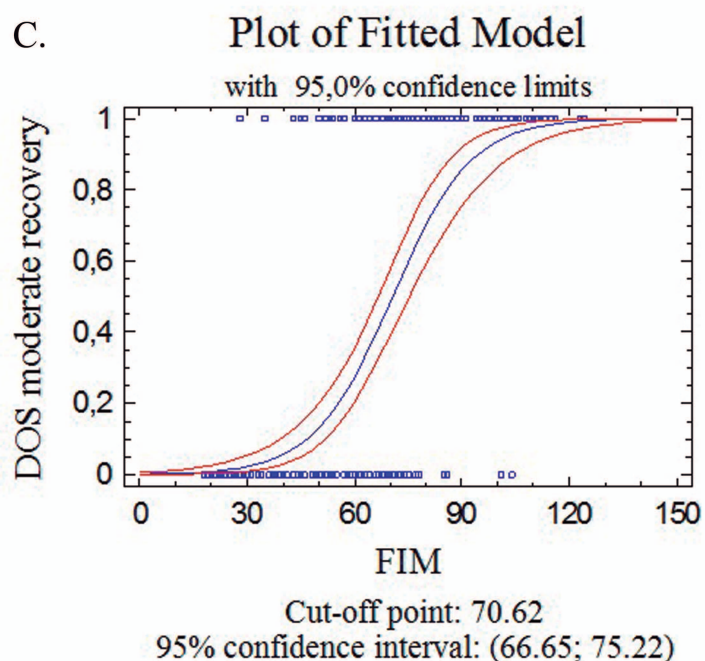
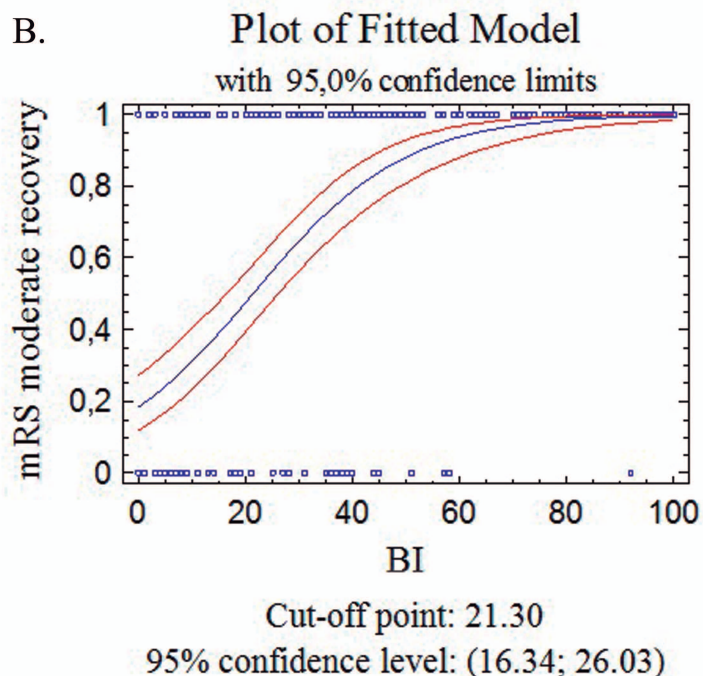
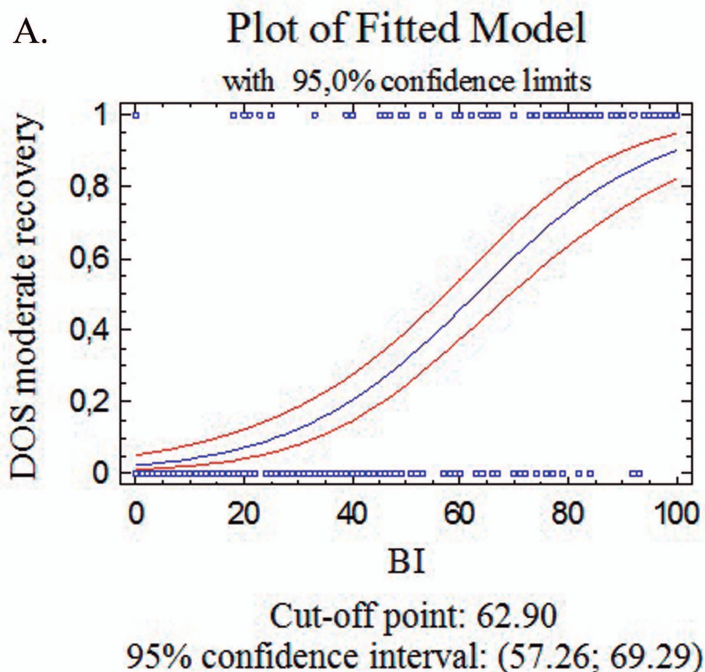
BI, FIM and FAM are valid and reliable measures of ADL and widely used instruments for longitudinal follow-up in poststroke outcomes. Translating schemes from global disability level to functional-ADL measures would facilitate better understanding of different degrees of disability from a population perspective. Thus, the cut-off scores found in this study, derived from the correspondence with the DOS and mRS scales, enable the categorization of functional-ADL scales, defining disability levels for poststroke population by means of functional measures or independence in ADL. Furthermore, the clinical interest of the correspondence between the different scales lies in the fact that determining the cut-off point could facilitate the clinical interpretation of the more continuous scales (BI, FIM and FAM).

### **Study limitations**

This study had several limitations. Although the baseline characteristics are most likely representative of patients in a specialized stroke care center, the subjects participating in this study had a significantly poor functional status than in comparable epidemiological studies. Additionally, we have focused solely on determining the lower cut-off point (separating severe and moderate disability), as practically no patient presented mild disability in our sample. Future research is needed on the generalizability of the categorization of functional-ADL assessment scales, to extend these findings to general poststroke population. Moreover, further studies should focus on determining the upper cut-off point (separating moderate and mild disability).

## **CONCLUSIONS**

In this study a high correlation between mRS and DOS was determined and the DOS scale was found to be more demanding than the mRS, in terms of patient independence. Additionally, the cut-off points separating the levels of severe and moderate disability in the functional-ADL scales BI, FIM and FAM (derived from the cut-off points of the global disability scales DOS and mRS) were determined. These findings would help practitioners and neurologists in poststroke clinical practice and would facilitate clinical interpretation of disability levels in different widely used assessment scales.



**Fig. 1.** Cut-off points and their 95% confidence intervals separating poor and moderate recovery for the BI, FIM and FAM scales, based on the DOS and mRS scales. A, Cut-off point for the BI based on the DOS. B, Cut-off point for the BI based on the mRS. C, Cut-off point for the FIM based on the DOS D. Cut-off point for the FIM based on the mRS E, Cut-off point for the FAM based on the DOS. F, Cut-off point for the FAM based on the mRS

**Table 1.** Contingency table of the recovery levels of the DOS and mRS scales.

		<b>mRS</b>		
		<b>Poor recovery</b>	<b>Moderate recovery</b>	<b>Good recovery</b>
<b>DOS</b>	<b>Poor recovery</b>	93 48.69%	98 51.31%	0 0.00%
	<b>Moderate recovery</b>	2 2.25%	84 94.38%	3 3.37%
	<b>Good recovery</b>	0 0.00%	0 0.00%	1 100.00%

**Kendall's tau-b = 0.475    p-value = 0.000**