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Predictive factors for ambulation in stroke patients in the rehabilitation setting: A multivariate analysis

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Abstract

Object: The purpose of this study was to investigate predictive factors for ambulatory recovery in stroke patients undergoing rehabilitation.
Methods: One hundred and eight-five first-stroke hemiplegics, admitted to an inpatient stroke rehabilitation program, were consecutively recruited to the study. Functional status at admission and discharge was evaluated by the Functional Independence Measure (FIM) and its motor component (motFIM), the upper and lower Motricity Index (upMI and lowMI), and the Trunk Control Test (TCT). The outcome variable was the Functional Ambulation Classification (FAC) score, assessed at discharge from rehabilitation. Multivariate analysis was used to assess the relationships between functional outcome (FAC), and the predictive variables.
Results: Up- and lowMI, FIM and motFIM, TCT and age at admission were significantly related to ambulatory recovery at discharge. Logistic regression analysis showed that the independent variables related to FAC were age, TCT and FIM: the model correctly allocated 86 out of 100 cases in the construction set and 76% of cases in the validation set. The ROC curve with logistic function output as the risk factor afforded very good accuracy (ROC area = 0.94), sensitivity = 86.5% and specificity = 85.4%.
Conclusions: Our results show that age and level of motor and functional impairment measured at baseline are significant predictors of ambulatory outcome. These findings promise to be of interest in goal optimization in the rehabilitation setting.

Keywords: Cerebrovascular disorders; Disability evaluation; Gait disorders; Neurologic; Outcome assessment (Health Care); Logistic models

1. Introduction

Stroke is the most common cause of adult disability in Italy; recent studies have shown that in Italy there are 194,000 new stroke cases every year and about 35% of them survive with important motor deficits [1,2]. This signifies a continuous increase in health care costs, particularly in terms of hospital care, nursing, and home assistance. These high incidence rates and large numbers of disabled individuals have led to an ever increasing demand for rehabilitation, paralleled with a growing need to optimize the efficiency and efficacy of limited resources [3]. Therefore, a valid prognosis for each stroke patient is needed as early as possible after stroke onset to initiate optimal rehabilitation according to realistic rehabilitation goals [4]. This applies in particular to recovery of ambulation, which is frequently affected in stroke patients and requires specific rehabilitation interventions. Regaining walking ability is of great importance to patients with stroke and is a major goal of all rehabilitation programs [5]. This is probably because changes in walking function are among the most frequent causes of physical dependency in these patients. Results have shown that 12 weeks after stroke, 95% of subjects reached their best function [6]. Wade et al. [7] who had used the Functional Ambulation Classification (FAC), found that 55% of stroke survivors achieved independent walking after 3 months, but 45% of patients were discharged with residual gait impairment [8]. Although many

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studies have been published, the prognostic factors in ambulatory recovery of stroke patients are not well defined, despite the fact that walking is a key goal in stroke rehabilitation [9]. Initial degree of severity of sensory and motor dysfunction of the paretic leg, disability at rehabilitation admission, urinary incontinence, sitting balance, and age are generally regarded as the most important predictors for walking recovery. However, it is not yet possible to accurately predict the occurrence and extent of motor ambulation recovery in individual patients during the (sub)acute phase of their stroke [10–13]. Nevertheless, knowledge about these predictors would be useful in selecting optimal rehabilitation treatment strategies for improving gait after stroke. The aim of this study was to identify factors that predict ambulatory recovery, as measured by the FAC score, in a group of subjects with ischemic or haemorrhagic stroke, admitted to intensive rehabilitation treatment.

2. Methods

2.1. Patient population

This study was based on 185 patients with hemiplegia at their first hemispheric stroke, consecutively admitted to inpatient rehabilitation treatment from January 2004 to December 2005. The diagnosis of stroke was based on clinical (presence of motor and possibly sensory deficits) and confirmed by instrumental assessment (computerized axial tomography or nuclear magnetic resonance), in accordance with World Health Organization criteria [14]. The recruited hemiplegic patients came directly from acute inpatient wards (intensive care, neurology, medicine). After pre-admission assessment by a physiatrist to evaluate clinical and social status, patients were placed on a waiting list for admission to the rehabilitation department and accepted as soon as possible. The inclusion criteria were: (1) history and clinical presentation (hemiparesis) of recent stroke (<8 weeks post-event); (2) a significant gait deficit as evidenced by <2 on the FAC scale (needs assistance); (3) sufficient cognition to be able to participate in training: a Mini-Mental State Exam (MMSE) score of 21 or higher; (4) a stable medical condition to allow participation in the test protocol and intervention; (5) ability to walk independently before the stroke. The exclusion criteria were: (1) patients with any comorbidity or disability other than stroke (i.e. amputation, orthopaedic disorders, spinal cord lesion) that would preclude gait training; (2) recent myocardial infarction (<4 weeks) or cardiac bypass surgery with complications; (3) any uncontrolled health condition for which exercise was contraindicated, such as consistent, uncontrolled diabetes or persistent, uncontrolled hypertension; (4) significant lower-extremity degenerative joint disease that would interfere with gait training; (5) cognitive impairment with an unfeasible or MMSE score <21; (6) history of bilateral cerebrovascular accident; (7) receptive aphasia or other cognitive problems that could hinder communication or cooperation; (8) presence or appearance of complications (cardiovascular, deep vein thrombosis, etc.) during hospital stay that might prevent the patient from undergoing rehabilitation treatment. All enrolled patients provided written or verbal informed consent, thus demonstrating sufficient ability to comprehend and motivation to participate.

Each patient was also characterized according to cognitive and stroke-related impairment. Cognitive impairment was evaluated by the MMSE, a brief, valid, reliable instrument [15]. We used a cutoff score of 21 on the MMSE, based on the report by Small et al. [16] to identify any cognitive impairment that would preclude participation in the study.

All recruited patients were treated by an interdisciplinary team (120–180 min per day, according to patient tolerance, for 5 days a week), with physiotherapy based on the Bobath concept [17].

2.2. Outcome assessment

A prospective observational study was defined, with all recruited subjects undergoing specific evaluation within 24 h of admission and of discharge from the rehabilitation centre. Evaluation was based on scales of demonstrated reliability, validity and sensitivity to change during post-stroke recovery, including the Motricity Index score, the Trunk Control Test and the Functional Independence Measure. Information was also gathered at admission on sociodemographic details (age, gender), presence of comorbid factors (arterial hypertension, hyperlipoproteinemia, diabetes), date and type of insult (ischemic or haemorrhagic), paralysed side and length of hospital stay.

The Motricity Index (MI) score is an ordinal weighted scale used to assess the severity of motor impairment to the upper (upMI) and lower (lowMI) extremities after a stroke [18]. Essentially it tests 6 limb movements while the patient is sitting on a chair or on the edge of the bed; if necessary, the patient may even be tested while lying down.

The Trunk Control Test (TCT) is a measurement scale which rates how far a subject is able to control trunk movements [19]. It assesses the patient's ability to roll to the weak side and to the strong side, to balance in a sitting position, and to sit up from lying down.

The Functional Independence Measure (FIM) is an ordinal scale that assesses severity of motor and neuropsychological disability, and amount of treatment needed for each patient admitted to a rehabilitation facility [20,21]. The FIM is composed of 18 items divided into 6 levels (minimum score 18; maximum score, equivalent to total functional independence: 126). Each item envisages 7 levels of performance independence (7, total independence and 1, total dependence or unassessable). The FIM can be subdivided into a 13-item motor subscale (motFIM) and a 5-item cognitive subscale (cognFIM). The scoring ranges for the motor and cognitive subscales are 13–91 and 5–35, respectively. The FIM assessment was based on the validated Italian version [22]. At the

Table 1
Description of the Functional Ambulation Classification (FAC) scores

Functional Ambulation Classification
0: Patient cannot walk
1: Patient requires physical assistance from one person, contacts are continuous
2: Patient requires physical assistance as in the previous category, but contact is intermittent or light
3: Patient requires verbal supervision or stand-by help from one person, without physical contact
4: Patient can walk independently on level ground but requires help on stairs, slopes, or uneven surfaces
5: Patient can walk independently anywhere

end of the rehabilitation programme, i.e. at discharge from the rehabilitation centre, an additional evaluation was made of functional walking recovery with the FAC scale, which is reliable, repeatable and sensitive to changes in stroke subjects [23].

The FAC is an ordinal scale with six assessment levels of walking disability (from category 0: nonfunctional ambulation, the patient is unable to walk to category 5: independent ambulation in which the patient is able to walk unaided) (Table 1). Classification by the FAC scale was used as the outcome measure for ambulatory recovery. The measurement scales were administered by the same health provider (RA): an expert in assessments, who had previously taken part in a training course qualifying him to use the scales with physiotherapy and nursing staff, who were also trained in the months prior to the survey.

2.3. Statistical analysis

Significant differences between groups were tested with Student's t for independent samples in the case of normally distributed variables, and with the Chi square test or Fisher Exact test for nominal qualitative variables. Linear correlations were analysed with Spearman's Rho tests. Logistic regression was performed to identify predictive factors for the dichotomized outcome in the construction set. The population of the construction set was divided into two groups: one group with poor outcome (48 patients with FAC categories of 0, 1 and 2), and one group with good outcome (52 patients with FAC categories of 3, 4 and 5). The function was then applied to the validation set and the results were compared. ROC curves were used to test sensitivity, specificity and accuracy of the Output of the Logistic Function (OLF; i.e. the result of the function, included between 0, the poorer result and 1, the best result) considered as the prognostic factor for ambulation recovery, on a 6-point rating scale. The categories had the following meaning: 1 (definitely negative: $\text{OLF} \leq 0.02$); 2 (probably negative: $0.02 < \text{OLF} \leq 0.05$); 3 (possibly negative: $0.05 < \text{OLF} \leq 0.50$); 4 (possibly positive: $0.50 < \text{OLF} \leq 0.95$); 5 (probably positive; $0.95 < \text{OLF} < 0.98$); 6 (definitely positive: $\text{OLF} \geq 0.98$). Statistical significance was set at $p < 0.05$. The statistics were performed using the STATISTICA 6 package by StatSoft Inc., 1994–2004.

3. Results

Consideration was taken of 150 of the total 185 subjects; the other 35 were excluded from the study because they did not meet the inclusion criteria. The population was split into two consecutive sets: the first (100 patients) was the construction set (to develop the model), the second (50 patients) was the validation set (to estimate the performance of the model) (Fig. 1). Table 2 shows the population's demographic and clinical characteristics and the median values of the upMI and lowMI, TCT, FIM and motFIM measured at admission and discharge from the rehabilitation centre. Mean time elapsing between the acute event and the admission to intensive rehabilitation unit was 25.8 ± 16.9 days (median: 20, range: 7–56) in the construction set and 26.6 ± 16.1 days (median: 22, range: 8–54) in the validation set. Mean hospital stay was 51.4 ± 29.5 days (median: 45, range: 12–120) in the construction and 54 ± 29.3 days (median: 45, range: 12–115) in the validation set. Monovariate analysis performed in the dichotomized construction set (poor outcome vs. good outcome), showed that age (rho = −0.37, $p < 0.0002$), upMI (rho = 0.54, $p < 0.00001$) and lowMI (rho = 0.66, $p < 0.00001$), TCT (rho = 0.71, $p < 0.00001$), FIM (rho = 0.78, $p < 0.00001$) and motFIM (rho = 0.78, $p < 0.00001$) admission values were all significantly correlated with walking ability at discharge, while no significant correlations were found with regard to paralysed side, gender, type of haemorrhagic/ischemic injury, hypertension, diabetes and hyperlipoproteinemia (Table 3). UpMI

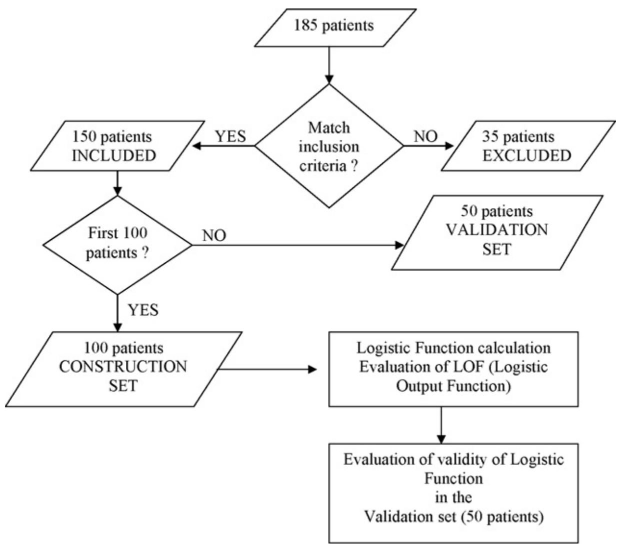

Fig. 1. Flow-chart of construction and validation set definition. The Logistic Function was calculated in the construction set and then evaluated in the validation set.

Table 2
Patient demographic and clinical characteristics measured at admission and at discharge from rehabilitation centre

Characteristic	Group construction set ($n = 100$)		Group validation set ($n = 50$)	
Gender (F/M)	49/51		21/29	
Mean (S.D.) age (years)	69 (12)		68 (11)	
Mean (S.D.) age (years)	66.7 (12)/71.7 (12)		68.4 (10.5)/68.2 (11.5)	
Type of stroke (H/I)	26/74		8/42	
Hemiplegia (L/R)	37/63		23/27	
Hypertension (Y/N)	74/26		39/11	
Diabetes (Y/N)	25/75		10/40	
Hyperlipoproteinemia (Y/N)	20/80		11/39	
Mean time (S.D.) between the acute event and the admission to intensive rehabilitation unit (days)	25.8 (16.9)		26.6 (16.1)	
Mean time (S.D.) between stroke and discharge from hospital (days)	77.9 (34.7)		80.8 (37.0)	
	Rehabilitation admission[a]	Rehabilitation discharge[a]	Rehabilitation admission[a]	Rehabilitation discharge[a]
UpMI (0–100)	35.5 (0–76)	57.5 (0–92)	18.0 (0–64)	53.5 (0–76)
LowMI (0–100)	42.0 (9–75)	65.0 (28–92)	33.5 (0–75)	64.5 (18–92)
FIM (18–126)	56.0 (26–83)	86.0 (52–108)	46.0 (25–68)	75.0 (52–102)
MotFIM (13–91)	30.0 (14–49)	63.0 (30–79)	25.5 (16–40)	52.5 (32–74)
TCT (0–100)	61.0 (24–93)	100.0 (61–100)	61.0 (24–87)	93.5 (61–100)

UpMI and lowMI: upper and lower Motricity Index; FIM and motFIM: Functional Independence Measure and its component motor; TCT: Trunk Control Test.
[a] Median (upper and lower quartile).

and lowMI, TCT, FIM and motFIM scores were all linearly correlated with each other (Rho values ranged from 0.59 to 0.96).

Logistic regression identified age, TCT and FIM as linearly independent risk factors, correctly allocating 86 out of 100 cases. In Table 4, the mean values of the risk factors before and after rehabilitation, are reported according to the FAC at discharge.

Considering the output of the logistic function as a risk factor, a ROC curve was built, yielding very good accuracy (ROC area = 0.94, CI 95%: 0.86–0.96, $p < 0.0001$), with sensitivity of 86.5% (CI 95%: 77–96%) and specificity of 95.5% (CI 95%: 75–95%) (Fig. 2). The function delivered in the construction set was tested in the validation set, providing correct allocation in 76% of cases (no statistical difference with the percentage of correct allocation in the construction set, $p = 0.14$). Considering the first category of OLF (i.e. def-

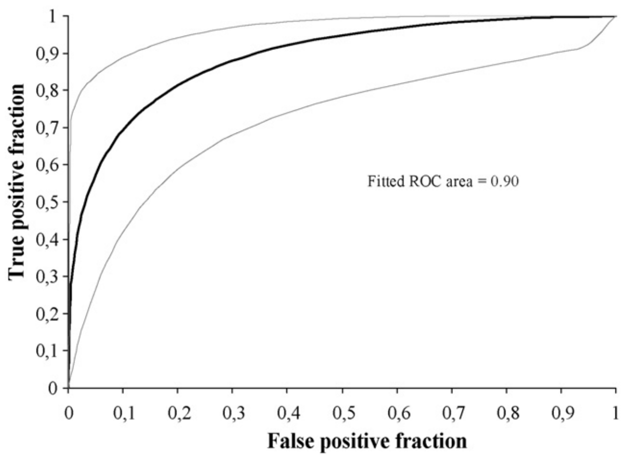

Fig. 2. ROC curve for output of the logistic function.

Table 3
Demographic and clinical characteristics in the two construction set groups

	Good outcome $n = 52$	Poor outcome $n = 48$	Statistic	p
Variables (mean ± S.D.)				
UpMI	57.94 ± 33.74	18.35 ± 27.83	Mann–Whitney	<0.000001
LowMI	64.46 ± 30.11	19.89 ± 25.03	*U*	<0.000001
FIM	78.21 ± 28.43	36.08 ± 18.23	test	<0.000001
MotFIM	49.67 ± 22.78	19.89 ± 9.26		<0.000001
TCT	79.02 ± 25.22	31.67 ± 26.09		<0.000001
Age	65.96 ± 12.64	72.60 ± 9.98	Paired T test	0.005
Variables				
Gender (F/M)	22/30	27/21	χ^2	0.16
Type of stroke (H/I)	38/14	34/14		0.802
Hemiplegia (L/R)	22/30	15/33		0.25
Hypertension (Y/N)	39/13	35/13		0.81
Diabetes (Y/N)	11/41	14/34		0.36
Hyperlipoproteinemia (Y/N)	13/39	7/41		0.19

uMI and lowMI: upper and lower Motricity Index; FIM and motFIM: Functional Independence Measure and its component motor; TCT: Trunk Control Test.

Table 4
Mean value of predictors, according to FAC in the construction and validation group

FAC	Construction group (100 pts)				Validation group (50 pts)			
	N	Age	FIM	TCT	*N*	Age	FIM	TCT
0	22	75.7 ± 10.6	26.7 ± 12.2 31.6 ± 13.0	17.1 ± 22.3 25.4 ± 24.1	13	71.7 ± 9.6	28.6 ± 14.3 33.5 ± 14.5	15.9 ± 24.9 35.8 ± 35.5
1	15	71.3 ± 9.5	43.3 ± 18.8 60.7 ± 23.8	49.9 ± 20.0 82.3 ± 17.0	6	72.5 ± 7.0	30.3 ± 18.9 51.8 ± 13.9	67.8 ± 13.4 78.5 ± 13.4
2	11	68.2 ± 7.8	44.9 ± 20.0 72.4 ± 15.4	35.8 ± 24.7 68.4 ± 29.0	8	66.4 ± 10.0	42.1 ± 15.8 76.1 ± 11.7	53.6 ± 26.6 75.9 ± 26.0
3	23	69.5 ± 11.6	58.5 ± 24.5 94.6 ± 13.9	71.7 ± 27.7 98.8 ± 3.9	6	74.5 ± 12.0	55.2 ± 23.2 86.0 ± 10.5	59.5 ± 29.6 97.8 ± 5.3
4	10	66.9 ± 10.7	88.9 ± 19.5 111.6 ± 8.0	87.0 ± 17.3 98.7 ± 4.1	5	66.8 ± 11.9	60.2 ± 19.3 86.2 ± 14.3	74.2 ± 27.2 94.8 ± 11.6
5	19	61.2 ± 13.8	96.5 ± 20.3 116.4 ± 7.6	83.6 ± 24.2 96.4 ± 12.3	12	61.5 ± 11.1	86.3 ± 21.5 114.6 ± 12.2	81.8 ± 25.5 100 ± 10.8

For Functional Independence Measure (FIM) and Trunk Control Test (TCT): in the first line, values at admission, in the second line, values at discharge.

initely negative: OLF ≤ 0.02) to belong to the group with FAC = 0 at discharge, included twelve out of 13 patients (92.3%) in the group with FAC = 0 at discharge in the construction set, giving an odds ratio of 92.4 (95% CI: 10.8–788), a sensitivity of 54.5% (CI 95%: 34–75%) and a specificity of 99% (CI 95%: 96–100%). In the validation set, 7 out of 8 (87.5%) patients with OLF ≤ 0.02 belonged to the group with FAC = 0 at discharge (odds ratio = 42, 95% CI 95%: 4.4–405, sensitivity = 54% CI 95%: 27–81%), specificity = 97% CI 95%: 92–100%).

4. Discussion

It is very important for rehabilitation clinicians to be able to predict motor and functional recovery after stroke, particularly from the point of view of optimizing specific interventions and available resource allocation [3]. In two recent reviews, Hendricks et al. [24] and Meijer et al. [25], pointed out that our knowledge on post-stroke motor and functional recovery is not yet sufficiently accurate, in either qualitative or quantitative terms. This knowledge may contribute to determining the best way patients with stroke should be treated with therapeutic exercise. This is particularly true for ambulatory recovery, which is a crucial objective in rehabilitation therapy for individuals with hemiplegia. No specific and commonly accepted walking assessment tool is available [26], thus the published studies on post-stroke gait recovery are based on many types of assessment tools, such as the Barthel Index score for walking, the FIM motor score, walking speed, etc. [27,28].

Our study was focused on identifying independent predictors of outcome measured by the FAC, that has proven [29] to be one of the most sensitive, reliable tools for measuring walking outcome at discharge from rehabilitation. Adding the time of rehabilitation care and the time elapsing between stroke and the start of rehabilitation, we obtained an overall mean total time between stroke and discharge from hospital of 79.0 ± 35 days, in agreement with several studies that have shown that most motor recovery occurs within the first 3 months post-stroke [30,31].

In our study, univariate analysis confirmed the findings of other works [4,32], i.e. that upMI, lowMI, TCT, FIM, motFIM and age measured at rehabilitation admission were significantly correlated with walking recovery measured on the FAC, rather like functional recovery of the upper limb [33,34]. As in the majority of the literature [13,27], our results suggested that gender, paralysed side, type of injury, hypertension, diabetes and hyperlipoproteinemia were not correlated with ambulatory recovery, whereas Lipson et al. [35] reported that haemorrhagic stroke patients were more inclined to experience ambulatory impairments.

Unlike other studies [4,36], in our survey the presence or absence of physical assistance for the patient was used to set the FAC-related population cutoff. Hence one group (poor outcome) included patients with FAC from 0 to 2 and the other group (good outcome) with patients from 3 to 5. Similarly to the findings reported by Wade et al. [7], approximately 2 months after stroke (on discharge from rehabilitation), 50% (75 out of 150) of our overall patient population showed good outcome. After this dichotomization, the logistic function was able to correctly allocate 86 out of 100 cases in the construction set, showing that age, the TCT and FIM were indeed independent risk factors (i.e.: they are the strongest predicting variables for independent gait at discharge from the rehabilitation setting). Since the outcome of the logistic function can be taken as the probability of correctly allocating patients from the test population to one of the two groups (good or poor outcome), we studied the ROC curve of the outcome of the logistic function as a risk factor; accuracy (ROC area = 0.94), sensitivity and specificity were very interesting. The same functions calculated in the construction set were tested in the validation set. There were no statistical differences in the correct allocation rate, and accuracy was good

(ROC area = 0.90). On comparing construction and validation set results, the calculated logistic function seems to have made a good estimation that can be generalized to new cases.

To optimize the efficacy and efficiency of rehabilitation interventions, it is also important to be able to identify those patients in whom rehabilitation will produce good or poor benefits in terms of ambulatory recovery. Kollen et al. [29] showed in particular that predicting non-ambulatory patients within the initial weeks proved to be much more difficult. Hence this model, unlike others [37], was able to identify at the time of admission to rehabilitation, patients with good or poor probability of independent ambulatory recovery at discharge from rehabilitation. This result will enable clinicians to more adequately plan treatment for each patient during their stay in the rehabilitation setting. Moreover, it is worth emphasizing that in the construction set, 92.3% (12 out of 13) of patients with OLF $\leq$ 0.02 belonged to the group with FAC = 0; this percentage did not differ (Fisher Exact test, $p = 0.63$) in the validation set (87.5%, 7 out of 8 pts). This means that about 54% (19/35) of patients with FAC = 0 at discharge are correctly detected by an OLF $\leq$ 0.02, with a specificity of 98% (CI 95%: 96–100%). Two patients out of 21 with OLF $\leq$ 0.02 obtained a FAC = 2: the first patient was 85 years old and increased his FIM from 42 to 65 while his TCT remained at 12, the second patient was 80 years old and increased his FIM from 25 to 85 and his TCT from 24 to 36. In both cases, FIM rose by far more than the mean (14.5 $\pm$ 15) increase in the group with poor outcome (FAC < 3). This brings us to a weakness in our study: no other measures of FIM and TCT were performed during hospitalization. Controlling the FIM and TCT dynamics might avoid these misclassifications.

For the group with FAC = 0 it would be more beneficial to target rehabilitation at more useful objectives, rather than seeking to achieve a goal which would be very hard to attain; it is worth considering that, probably with a shorter hospital stay, the same patients could have achieved objectives such as help in transfers (transfer from bed to wheelchair, transfer from wheelchair to WC, etc.) which significantly aid, for example, home-based patient management. From this standpoint, the possibility of predicting the studied logistic function is interesting and useful: obviously high specificity rather than high sensitivity is to be preferred.

The group with good outcome could achieve better results from an early, intensive, global rehabilitative approach, focusing on exercises oriented towards early ambulatory recovery. For example, in agreement with Kollen et al. [37], we could develop a programme for early recovery of postural control of standing, which is more important in terms of regaining gait than recovery of muscular strength.

To conclude, our results could thus help to design optimal rehabilitation programmes based on realistic therapeutic goals and optimize the efficiency and efficacy of limited resources.

Lastly, our work presents other limits: the first is that it does not consider ambulatory outcome in the post-discharge period (at 6 months' follow-up), but this was not one of the study's objectives. This goal is part of an ongoing study. The second weakness is that our study was limited to a homogeneous group of patients with hemiplegia and may thus have the restricted external validity of developed models. The third limit is that the study fails to assess the effects of various rehabilitation intervention methods on ambulatory recovery. This, too, is the objective of an ongoing multicentre study.

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