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RESEARCH ARTICLE

Recovery of Postural Control and Gait After a Severe Stroke. A Descriptive Study

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ABSTRACT

Background and Purpose: Research into recovery of postural control after a severe stroke needs to be improved. The objective is to describe postural control at admission and the recovery of postural control during rehabilitation according to gait assistance required at discharge of subacute rehabilitation in subjects with severe motor impairment after a stroke.

Methods: A descriptive longitudinal retrospective study was conducted. Subacute post-stroke patients who could not walk without physical assistance at admission were included (n = 151). Recovery during rehabilitation is described in terms of Absolute Recovery (AR) and Relative Recovery (RR). AR and RR were calculated with Berg Balance (BBS) at admission and at discharge. Gait performance was assessed using the Functional Ambulation Category. A secondary analysis was conducted in the subgroup of subjects with an admission BBS less than 6 (n = 106).

Results: Postural control at admission, AR and RR showed statistically significant differences between groups according to gait assistance requirement at discharge ($p < 0.05$). In subjects with BBS less than 6 at admission, differences were similar for RA and RR ($p < 0.05$). For BBS at admission, statistically significant differences were found between assisted gait group with supervised or independent group; however, statistical differences were not found ($p > 0.05$) between those patients that achieved a supervised gait and independent gait at discharge.

Discussion: The results of this study could be a new step to evince why longitudinal analysis is needed during stroke rehabilitation in subjects with severe motor impairments after a stroke. The clinical relevance of BBS at admission in this population may be rethought.

1 | Introduction

Stroke is a pathology with high prevalence and mortality worldwide [GBD 2019 Stroke Collaborators et al. 2021]. In this context, the recovery and rehabilitation of people who have suffered a stroke has become the next frontier in stroke medicine [Bernhardt et al. 2016]. Furthermore, direct and indirect costs generated by stroke treatment increase. Among these costs is inpatient rehabilitation. People who are not in optimal motor condition to return home after a stroke are those who most justify inpatient rehabilitation. However, admission to an inpatient rehabilitation program, the duration of the program, and discharge from the program are not clearly defined concepts [Xian et al. 2017; Cormier et al. 2016; Reistetter et al. 2010].

One of the main objectives of rehabilitation after a stroke is to optimize mobility [Stinear et al. 2019]. Optimizing mobility can minimize the burden of disability on the person, their family, and the community to which they belong. A central motor aspect in the recovery of mobility in people who have suffered a stroke is the recovery of postural control. Postural control has been related to different aspects of motor behavior, among which gait can be highlighted [Kwakkel et al. 2023]. Different algorithms or models have been reported for predicting the recovery of gait based on the initial conditions of postural control after a stroke. These algorithms or models are based on the relationship of postural control in the first days or weeks post-stroke with the recovery of gait after a certain time. In patients with moderate to mild motor impairment, these algorithms or models would be accurate. However, in patients with moderate to severe impairments, predictions based on initial conditions may be inaccurate [Kwakkel et al. 2023]. To be noted, poor postural control in the first days or weeks after a stroke does not necessarily mean that the person cannot improve his or her walking ability during rehabilitation [Gath et al. 2023]. The level of recovery of postural control after a severe stroke can be heterogeneous. This heterogeneous evolution after a stroke justifies the recommendation of repeated evaluation over time [Kwakkel et al. 2017, 2023; Pohl et al. 2021]. For this same reason, the development of longitudinal studies that analyze motor recovery after a severe stroke is also recommended [Kwakkel et al. 2017, 2023; Pohl et al. 2021].

An underexplored option for describing motor recovery after a severe stroke could be in terms of absolute or relative recovery during rehabilitation on a specific motor scale [Mosalski et al. 2021]. For example, analysis of absolute or relative recovery on a scale assessing postural control could be useful in describing gait recovery after stroke. Furthermore, since motor recovery after a stroke can be heterogeneous, the analysis of postural control recovery in absolute and relative terms could be an alternative to improve the decision-making process in clinical practice.

The main objective of this study was to describe postural control at admission and the recovery of postural control during rehabilitation according to gait assistance required at discharge of subacute rehabilitation in subjects with severe motor impairment after a stroke. Firstly, a description is done with patients who required physical assistance to walk or cannot walk at the admission of subacute inpatient rehabilitation regardless of the Berg Balance Scale (BBS) scored at admission. A second description is done with those patients who required physical assistance to walk or cannot walk and showed a BBS below 6 at the admission of subacute inpatient rehabilitation.

2 | Methods

2.1 | Study Design

A longitudinal retrospective descriptive cohort study was conducted. Patients with a stroke diagnosis discharged from a Rehabilitation Center between January 2016 and December 2023 were analyzed. Data were extracted from the statistical database of the stroke area of the Physical Therapy Service.

2.2 | Subjects

In order to be included in the study patients had to comply with the following requirements by the time of admission to the Rehabilitation center: (1) be over 18 years old, (2) medical diagnosis of first unilateral supratentorial stroke, (3) have a Functional Ambulation Category < 3 upon admission (does not walk or requires physical assistance to walk), (4) up to 90 days between the date of the stroke and the date of admission to the Rehabilitation Center. The exclusion criteria comprised: (1) having another neurological disorder, history of orthopedic disability or psychiatric condition, (2) having been referred to other institutions due to clinical instability, patients who discontinued the rehabilitation program or deceased patients, and (3) missing data.

At the Rehabilitation Center where the study has been conducted, patients receive an interdisciplinary intensive rehabilitation program. The patients receive two 50-min sessions of individual and personalized physical therapy from Monday to Friday and another 50-min shared therapy on Saturdays or holidays. All patients underwent conventional repeated task-oriented training with progressive efforts tailored to functional capacity and oriented toward activities related to the patient's specific motor goals. The center's physical therapists are constantly updating their knowledge of motor neurorehabilitation concepts and techniques. Intradisciplinary and interdisciplinary meetings are held weekly to establish goals and discuss the treatment provided to patients.

2.3 | Measurements

Postural control: to evaluate the postural control, the Berg Balance Scale (BBS) was used. The BBS is a balance functional test comprised of 14 items, where each item may range from 0 to 4 adding a total score of up to 56 points. It assesses static balance in sitting and standing positions as well as dynamic balance in transitions and in standing positions, in addition to assessing the ability to make postural adjustments in preparation for reaching or stepping positions [Blum and Korner-Bitensky 2008]. The higher the score achieved by the subjects, the better the postural control performance.

For the analysis of the recovery of postural control during rehabilitation, two variables are defined:

1. *Absolute Recovery (AR)*: the difference between the BBS on discharge from the program and the BBS on admission.

$$\text{AR} = \text{BBS on discharge} - \text{BBS on admission}$$

AR is the recovery of postural control in absolute terms with respect to improvement in BBS during the program.

2. *Relative Recovery (RR)*: it is defined as the quotient between absolute recovery and the missing score to reach the BBS ceiling upon admission multiplied by 100.

$$\text{RR}\ (\%) = \frac{\text{BBS on discharge} - \text{BBS on admission}}{56 - \text{BBS on admission}} * 100$$

RR is the recovery of postural control in relative terms with respect to the improvement in BBS during the program. RR shows how much of the BBS score was recovered relative to what was missing to obtain a score of 56 on admission.

Ambulation category: measured by the Functional Ambulation Category (FAC) scale. The FAC is a reliable and valid ordinal scale to classify the level of physical assistance a patient needs to ambulate safely. It consists of 6 levels (0–5): category 0 corresponds to patients who do not walk (or require physical assistance from two people to walk), category 1 with continuous assistance, 2 with intermittent assistance, 3 with supervision, 4 with independence, but requires assistance or supervision on irregular surfaces, and category 5 corresponds to independent subjects on regular and irregular surfaces, including inclined planes or stairs [Mehrholz et al. 2007]. Gait achievement at discharge was grouped according to the level of assistance required: physically assisted gait (the group of patients categorized FAC 0, 1 or 2), supervised gait (the group of patients categorized FAC 3), and independent gait (the group of patients categorized FAC 4 or 5).

To improve the description of the studied sample, different demographic and clinical variables were considered. To complete the description of motor behavior, the Fugl Meyer Assessment (FM) was also considered [Duncan et al. 1983]. All tests used in this study have been shown to be reliable, valid, sensitive and recommended in subjects who have suffered a stroke [Duncan et al. 1983; Mehrholz et al. 2007; Blum and Korner-Bitensky 2008; Kwakkel et al. 2023]. Such tests are systematically conducted by trained professionals within 24 h of the patients' admission and discharge from the Rehabilitation Center.

2.4 | Statistical Analysis

A descriptive analysis was performed of the clinical-demographic characteristics, motor outcomes, AR and RR of all participants according to the three established groups considering the assistance required to walk at discharge (physically assisted, supervised and independent). For qualitative variables, frequency and percentages were reported. The Chi-square test was not applicable in all cases for qualitative variables because in some cases the assumptions of the test were not met. For quantitative variables, after using the Shapiro-Wilks test to assess normality, the median and interquartile ranges were reported. To compare groups, after controlling the Anova test assumptions, Kruskal Wallis test was performed. Finally, multiple pairwise comparisons among groups were determined using the Dunn test. The analysis was performed first on the entire sample and then on the subgroup of subjects who had a Berg Balance score of less than 6 upon admission (the lowest score for postural control determined by TWIST algorithm) [Smith et al. 2022].

All analyses performed in this work took significance level $\alpha = 0.05$. The statistical program R version 4.3.3 was used for the analysis.

2.5 | Ethical Considerations

The study was approved by the Ethics Committee of the Rehabilitation Center where it was carried out (approval number: XXX). It counted on the exception of the informed consent requirement since it concerns a retrospective study based on institutional records. This study was subject to the good clinical practice regulations according to the Declaration of Helsinki of the World Medical Association (n.d.). [World Medical Association declaration of Helsinki].

3 | Results/Findings

3.1 | Subjects

A total of 151 patients comprised the final sample (Figure 1 shows the flowchart for the patient's inclusion and exclusion). All patients on admission required physical assistance to walk or were unable to walk (FAC < 3) regardless of the BBS score at admission. The ambulation performance according to the gait assistance requirement at discharge: 52 patients (34.5% of the total sample) needed physical assistance to walk (FAC 0: $n = 20$, 38.5%; FAC 1: $n = 14$, 26.9%; FAC 2: $n = 18$, 34.6%), 62 patients (41% of the total sample) needed supervision to walk, and 37 patients (24.5% of the total sample) could walk independently (FAC 4: $n = 29$, 78.4%; FAC 5: $n = 8$, 21.6%).

The subgroup of patients who upon admission required physical assistance to walk or cannot walk (FAC < 3) and showed a BBS below 6 was 106 subjects. The ambulation performance according to gait assistance requirement at discharge of this subgroup: 49 patients (46.2% of the subgroup) needed physical assistance to walk (FAC 0: $n = 20$, 40.8%; FAC 1: $n = 14$, 28.6%; FAC 2: $n = 15$, 30.6%), 41 patients (38.7% of the subgroup) needed supervision to walk, and 16 patients (15.1% of the subgroup) could walk independently (FAC 4: $n = 15$, 93.7%; FAC 5: $n = 1$, 6.3%).

3.2 | Postural Control at Admission, AR and RR in the Entire Sample

Table 1 shows the description of the clinical, demographic and motor outcomes analyzed in patients who could not walk without physical assistance (FAC < 3) at admission. BBS at admission and AR and RR showed statistically significant differences ($p < 0.05$) between the three groups regarding requirements at discharge of rehabilitation for physical assistance to walk or supervision or independence. Figures 2 and 3 show the boxplot for AR and RR according to gait performance at discharge.

3.3 | Postural Control at Admission, AR and RR in the Subgroup

Table 2 shows the description of the clinical, demographic and motor outcomes analyzed in patients who could not walk without physical assistance (FAC < 3) and evinced a BBS below 6 at admission. BBS at admission showed statistical differences ($p < 0.05$) between those who walk physically assisted and those who walk with supervision or independence. Statistical differences were not found ($p > 0.05$) for BBS at admission between those with supervised gait and those with independent gait at discharge. AR and RR showed statistically significant

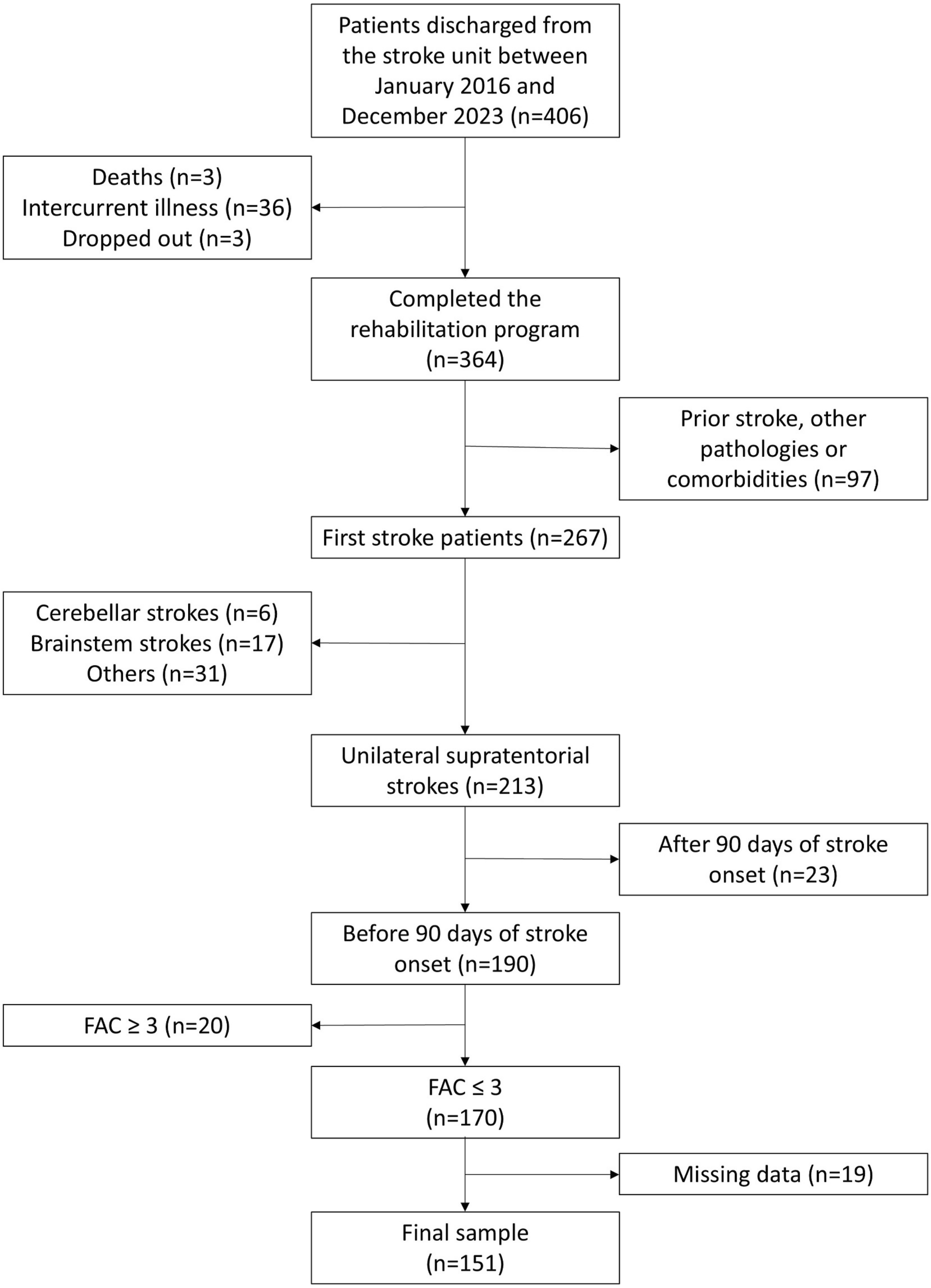

FIGURE 1 | Flowchart of participants for inclusion.

differences (p < 0.05) between the three groups regarding requirements at discharge of rehabilitation for physical assistance to walk or supervision or independence.

4 | Discussion

According to the results evinced in this study, a longitudinal analysis of the recovery of postural control during inpatient rehabilitation may improve the description of gait recovery in subacute patients with severe motor impairment after stroke. To our knowledge, this is the first descriptive study that analyzed Absolute and Relative Recovery of postural control as an option to be considered during inpatient rehabilitation. Furthermore, it is first evinced that Absolute and Relative Recovery of postural control may be more descriptive of gait achievement than BBS at admission in subacute patients with severe motor impairment after stroke.

TABLE 1 | Characteristics of the total sample and divided by gait assistance requirement at discharge.

	Total sample (n = 151)	Physically assisted (n = 52)	Supervised (n = 62)	Independent (n = 37)	p-value
Age (years), median (IQR)	65 (53–73)	70 (64–76)*,**	63 (51–71)	56 (47–67)	0.001
Gender, n (%)					
Male	93 (61.5)	33 (63.5)	37 (59.7)	23 (62.1)	0.914
Female	58 (38.5)	19 (36.5)	25 (40.3)	14 (37.9)	
Stroke type, n (%)					
Ischemic	122 (80.8)	45 (86.5)	50 (80.6)	27 (73)	0.277
Haemorrhagic	29 (19.2)	7 (13.5)	12 (19.4)	10 (27)	
Lesion side, n (%)					
Right	74 (49)	30 (57.7)	28 (45.2)	16 (43.2)	0.296
Left	77 (51)	22 (42.3)	34 (54.8)	21 (56.8)	
Days since stroke, median (IQR)	20 (13–31)	27 (18–37)*,**	16 (11–29)	17 (13–25)	0.001
Length of stay (days), median (IQR)	113 (60–156)	137 (83–178)**	122 (59–155)**	65 (45–95)	0.001
Initial FM UL, median (IQR)	4 (4–12)	4 (4–4)*,**	4 (4–13)**	8 (4–54)	0.001
Final FM UL, median (IQR)	13 (6–48)	5 (4–8)*,**	15 (9–45)**	54 (28–65)	0.001
Initial FM LL, median (IQR)	8 (4–16)	4 (4–8)*,**	9 (6–16)**	17 (8–26)	0.001
Final FM LL, median (IQR)	22 (13–29)	10 (8–15)*,**	22 (18–28)**	30 (26–33)	0.001
Initial FAC, n (%)					
0	121 (80.2)	50 (96.2)	50 (80.7)	21 (56.8)	n/a
1	25 (16.5)	2 (3.8)	10 (16.1)	13 (35.1)	
2	5 (3.3)	0	2 (3.2)	3 (8.1)	
BB at admission, median (IQR)	4 (1–7)	1 (0–3)*,**	4 (3–7)**	7 (4–17)	0.001
BB at discharge, median (IQR)	38 (15–49)	6 (4–15)*,**	40 (35–47)**	54 (50–54)	0.001
Absolut recovery of BB, median (IQR)	30 (11–40)	5 (3–14)*,**	33 (26–40)**	44 (36–49)	0.001
Relative recovery of BB (%), median (IQR)	65 (23–86)	9 (5–25)*,**	70 (55–80)**	94 (87–96)	0.001

Abbreviations: BB: Berg Balance Scale; FAC: functional ambulation category; FM LL: fugl meyer lower limb; FM UL: fugl meyer upper limb; IQR: interquartile range; n/a: not applicable, the chi-square assumptions are not met.
*$p < 0.05$ (statistically significant difference with supervised group).
**$p < 0.05$ (statistically significant difference with independent group).

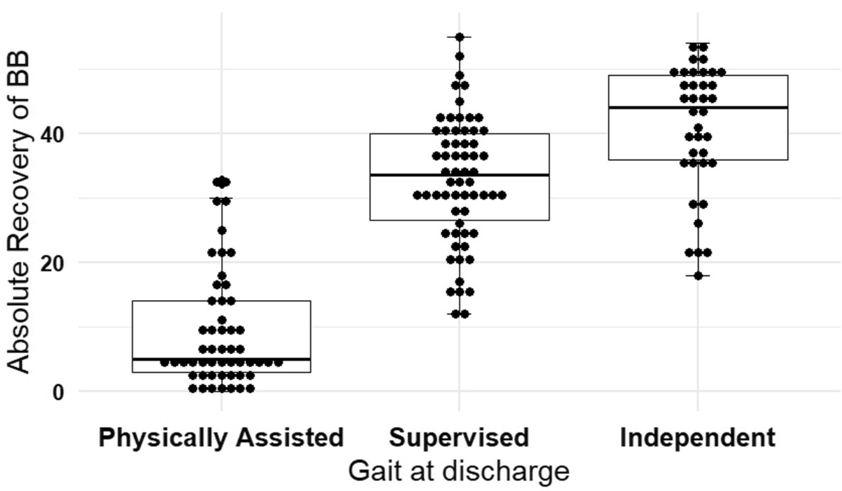

FIGURE 2 | Absolute recovery of berg balance scale (BB) during inpatient rehabilitation according to gait functionality at discharge.

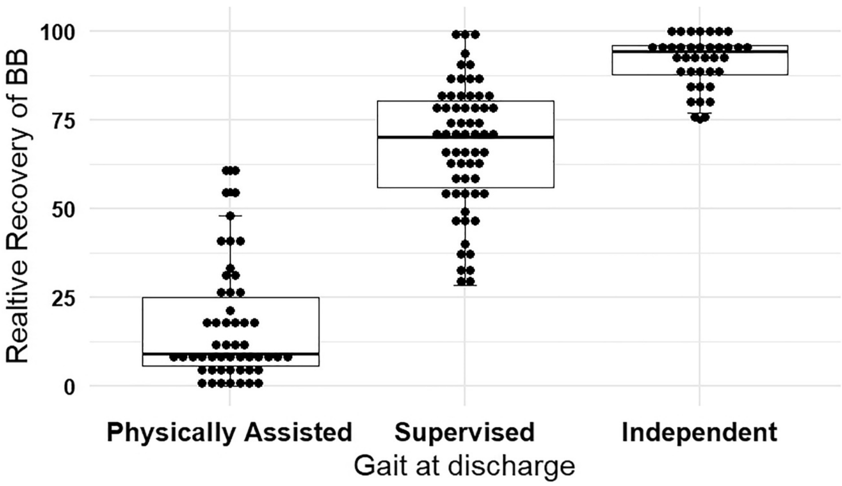

FIGURE 3 | Relative recovery of berg balance scale (BB) during inpatient rehabilitation according to gait functionality at discharge.

TABLE 2 | Characteristics of the subgroup of subjects with Berg Balance below 6 at admission according to gait assistance requirement at discharge.

	Subgroup (n = 106)	Physically assisted (n = 49)	Supervised (n = 41)	Independent (n = 16)	p-value
Age (years), median (IQR)	67 (56–73)	70 (64–76)*,**	66 (53–71)**	48 (43–59)	0.001
Gender, n (%)					
Male	63 (59.5)	30 (61.2)	24 (58.5)	9 (56.3)	0.929
Female	43 (40.5)	19 (38.8)	17 (41.5)	7 (43.7)	
Stroke type, n (%)					
Ischemic	85 (80.2)	42 (85.7)	34 (82.9)	9 (56.3)	0.03
Haemorrhagic	21 (19.8)	7 (14.3)	7 (17.1)	7 (43.7)	
Lesion side, n (%)					
Right	53 (50)	28 (57.1)	18 (43.9)	7 (43.8)	0.394
Left	53 (50)	21 (42.9)	23 (56.1)	9 (56.2)	
Days since stroke, median (IQR)	24 (13–34)	27 (18–37)*	15 (11–34)	18 (13–26)	0.009
Length of stay (days), median (IQR)	136 (79–169)	138 (95–181)**	140 (107–169)**	73 (60–112)	0.001
Initial FM UL, median (IQR)	4 (4–6)	4 (4–4)**	4 (4–12)**	5 (4–9)	0.001
Final FM UL, median (IQR)	8 (4–21)	5 (4–8)**	12 (8–43)**	32 (13–60)	0.001
Initial FM LL, median (IQR)	6 (4–10)	4 (4–8)*,**	8 (6–13)	9 (5–14)	0.001
Final FM LL, median (IQR)	17 (10–24)	10 (8–14)*,**	21 (17–28)**	28 (23–30)	0.001
FAC at admission, n (%)					
0	103 (97.2)	49 (100)	39 (95.2)	15 (93.8)	n/a
1	3 (2.8)	0 (0)	2 (4.8)	1 (6.2)	
2	0 (0)	0 (0)	0 (0)	0 (0)	
BB at admission, median (IQR)	3 (1–4)	1 (0–3)*,**	4 (1–4)	4 (2–4)	0.001
BB at discharge, median (IQR)	29 (6–43)	6 (4–14)*,**	40 (31–45)**	53 (48–54)	0.001
Absolut recovery of BB, median (IQR)	25 (5–39)	4 (3–11)*,**	36 (30–41)**	48 (45–50)	0.001
Relative recovery of BB (%), median (IQR)	48 (9–76)	7 (5–21)*,**	69 (53–78)**	94 (85–96)	0.001

Abbreviations: BB: Berg Balance Scale; FAC: functional ambulation category; FM LL: fugl meyer lower limb; FM UL: fugl meyer upper limb; IQR: interquartile range; n/a: not applicable, the chi-square assumptions are not met.
*$p < 0.05$ (statistically significant difference with supervised group).
**$p < 0.05$ (statistically significant difference with independent group).

On the one hand, Absolute and Relative Recovery of BBS showed statistically significant differences between the three groups according to assistance requirements to walk at discharge in the entire sample and in those patients with BBS below 6 at admission. On the other hand, BBS at admission also showed statistically significant differences between groups for the total sample but not for the subgroups of patients with a BBS below 6 at admission. Differences in AR (Absolute Recovery of BBS during rehabilitation) are clinically relevant for the whole sample according to gait performance at discharge. However, the differences may be at least debatable as to whether they are clinically relevant to BBS at admission in the entire sample (even more so in the subgroup sample). The minimum detectable change in BBS would be between 5 and 7 points [Stevenson 2001]. Moreover, in patients with BBS below 6 at admission, differences in BBS at admission are directly not statistically significant between achieving supervised or independent gait at discharge. It could be thought that it is a methodological restriction because patients studied in the subgroup were those with BBS below 6 at admission. However, since this is the lowest level of postural capabilities, the restriction is not methodological but rather a motor restriction concomitant with suffering a severe stroke. This study shows that many stroke survivors that are in the lowest control postural capabilities could also describe a longitudinally relevant recovery.

It is important to note that the stroke rehabilitation literature is replete with studies developing algorithms or models based on the relationship of postural control in the first week with the recovery of independent gait after a certain time [Kwakkel et al. 2023]. Stroke patients that evinced a BBS below 6 1 week after the stroke are those with a low probability of regaining independent gait within the first 6 months (according to the remarkable algorithm called TWIST) [Smith et al. 2022]. For example, in the first week after a stroke, a TWIST score of 1 out of 4 means that 1 in 5 subjects would achieve independent walking in 6 months. If 1 in 5 severe stroke patients can walk independently after 6 months, is independent gait a realistic goal for patients with severe motor impairment after a stroke? Independent gait could be a realistic goal for a wide number of subjects that suffer a stroke although not for those with severe motor impairment. That is why supervised gait achievement would be more clinically relevant in patients with severe motor impairment after a stroke. Noteworthy, in this study, 41% of the subjects analyzed achieved supervised gait (FAC = 3) and 24.5% achieved independent gait (FAC > 3). Patients who achieve supervised gait are those who can return home with the ability to walk inside their home with supervision. This is good news for the patient (that can feel the recovery of gait without physical assistance) and good news for caregivers due to the reduction in physical assistance required by the patient. The results of this study show that a longitudinal analysis could be complementary useful in severely affected individuals after a stroke. Especially, to decide if supervised gait achievement is a realistic goal.

Differences in the length of stay in intensive inpatient rehabilitation based on gait achievement at discharge are also described. This could mean that if a patient quickly reaches a high level of FAC, the decision to plan inpatient rehabilitation discharge would be quicker or easier. In this study, those that at best achieved physically assisted gait at discharge showed a refractory response to recover postural control (despite having a longer length of stay). This refractory response in some patients could be a reason to believe that, in severely affected post-stroke patients, it is relevant to design rehabilitation programs in a dynamic way considering longitudinal outcomes (such as Absolute Recovery or Relative Recovery of BBS). To be noted, statistical differences were not found in the length of stay between those patients who achieved supervised gait and those who achieved physically assisted gait. However, statistical differences were found between Relative and Absolute Recovery. Attention should be paid to Absolute and Relative Recovery of BBS to perform a differential description of the achievement of physically assisted gait and supervised gait after severe stroke. Absolute and Relative Recovery of BBS could also be considered to decide realistic goals and discharge planning during inpatient rehabilitation for people with severe motor impairment after a stroke.

It is also important to note that repeated assessments after a stroke are based solely on expert surveys and not on scientific evidence studies [Kwakkel et al. 2023]. There is still a significant evidence gap regarding why and how assessments should be repeated during rehabilitation programs. The results of this study highlight the usefulness of longitudinal analysis of subacute recovery after a stroke. More studies are needed to reinforce the importance of AR and RR and their relationship to different important variables such as age and time since stroke or others. To be noted, this is a descriptive study, and the analysis of association or causal relationships is not an aim of it. More elementary studies (such as descriptive ones) are still needed in post-stroke rehabilitation research. Even more so if knowledge gaps persist, which may be one of the reasons why trials of motor interventions after stroke have failed in the last few years [Stinear et al. 2020]. More studies focused on subjects that suffer from severe stroke are also needed. This population is frequently excluded from research despite being the one that may need the most resources from the health system. Finally, future studies may provide data on longitudinal recovery of postural control in terms of specific time frames after a severe stroke.

4.1 | Limitations

One of the main limitations of this study is that it was conducted in a single rehabilitation center. Secondly, the fact that this is a retrospective study may also be considered a limitation. Another limitation could be the non-inclusion of other pathophysiological aspects that may also describe gait at discharge, such as size of the lesion, comorbidities, brain areas affected, cognitive conditions, or conditions related to language.

4.2 | Implications for Physiotherapy Practice

Initial postural control conditions may be non-relevant in describing gait recovery during inpatient rehabilitation in people who have suffered a severe stroke. A complementary analysis in patients with severe motor impairment seems necessary to demonstrate results during a rehabilitation program. Absolute and Relative Recovery of BBS during inpatient rehabilitation are longitudinal observations that showed different levels of recovery between those patients who achieved supervised or independent walking and those who did not. Moreover, Absolute Recovery and Relative Recovery are simple calculations that could help in the decision-making process during inpatient rehabilitation.

Author Contributions

Christian Gath: conceptualization, data curation, formal analysis, methodology, project administration, writing – original draft, writing – review and editing. **Matías Gianella:** data curation, writing – review and editing. **Marcelo Gatti:** conceptualization, writing – review and editing. **Maria Elisa Rivas:** conceptualization, methodology, supervision, writing – review and editing.

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Funding

The authors have nothing to report.

Ethics Statement

The study had ethics approval from the Fleni Ethics Committee (approval number: 013/24). This study was subject to the good clinical practice regulations according to the Declaration of Helsinki of the World Medical Association.

Consent

The study counted on the exception of the informed consent requirement since it was a retrospective study based on institutional records.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Anonymized data can be made available by request to the corresponding author upon reasonable request. The authors will share the data with qualified investigators whose proposal for data use has been approved by an independent review committee.

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