The cognitive level does not interfere with recovery after robot-assisted gait training in Traumatic Brain Injury: A 10-year cohort study

ABSTRACT

BACKGROUND:

There is still no clear evidence available on the role of robot-assisted gait training (RAGT) in severe traumatic brain injury (TBI) and on the relationship between this intervention and cognitive impairment.

OBJECTIVE:

This study investigates the impact of cognitive level at admission on functional recovery in a cohort of patients with severe TBI who received RAGT training within a multidisciplinary rehabilitation setting.

METHODS:

We included patients with gait disturbance due to a severe TBI. Patients were grouped into three classes according to their level of cognitive functioning (LCF) at admission (LCF 2-3; LCF 4-5-6; LCF 7-8). We collected demographics (sex, age), clinical data, and a set of outcome measures at admission and discharge.

RESULTS:

We registered 80 patients, 19 females and 61 males, 35.3 ± 14.85 years. Patients with a low cognitive level at admission were mostly subacute ($p = 0.001$). Cognitive impairment despite longer length stay in the hospital (LOS) ($p=0.001$) did not preclude recovery after RAGT in terms of cognition ($R2 = 0.68$; $p < 0.0001$), functional independence ($R2 = 0.30$; $p < 0.0001$) and overall disability ($R2 = 0.32$; $p < 0.0001$).

CONCLUSION:

Irrespective of their level of cognition, patients with severe TBI might benefit from RAGT during a multidisciplinary program.

Key words: Traumatic brain injury, Robot-assisted gait training, Cognition, Multidisciplinary rehabilitation, Disability.

INTRODUCTION

Traumatic brain injury (TBI) is a common cause of neurological damage and disability that affects the medical, social and economic spheres. To date, according to recent epidemiological studies, TBI incidence rate in Europe is estimated between 83.3 and 849 per 100.000 of the population per year (regional-level studies) [1] .Cognitive impairment is usually also a consequence of brain trauma. In the case of moderate and severe TBIs, statistics indicate cognitive sequelae in approximately 65% of patients, and physical sequelae in 40% of patients. Even in cases of mild TBI without visible physical sequelae, 43% of people suffer from cognitive impairments [2, 3]. The parts of the brain that are most commonly affected in traumatic brain injuries are the frontal and temporal lobes [4]; the frontal lobe is considered the crucial neural substrate for cognitive and social behaviour. For this reason, assessment of patients following a severe TBI maintains a focus on disorders of consciousness outcomes [3].

Pilot studies have shown that patients with TBI have good cognitive and functional recovery through rehabilitation, especially young patients in the acute phase [5]. Other studies have shown high correlation between cognitive recovery and functional improvement in these patients [6, 7]. The past two decades have seen the introduction of new rehabilitation interventions that are based on the use of robotics. RAGT is intended to allow the patient to practice more ‘normal’ gait patterns. Robotic exoskeletons can provide the user with intensive, goal-directed movement repetition and stability and balance during gait, compared to conventional physical therapy. Robot-assisted therapy helps patients to accelerate functional recovery [8, 9]. The use of robotic technology combined with conventional rehabilitation is an added value that not only improves patients’ mobility, but also allows health professionals to organise their work better [10-12]. Moreover, RAGT can potentially improve the gait pattern and to increase the volume of patients' exercise while relieving the therapist's physical load, and shortening the duration of hospitalization [13]. So far, studies have reported a potential beneficial effect of RAGT in patients with TBI, both in terms of walking function and of gait symmetry [8, 11, 14]. Moreover, this intervention seems to be safe and feasible even in patients with severe TBI with disorders of consciousness, with positive effects on cognition. The main objective of this observational study is to investigate the influence of the cognitive level at admission on a variety of outcomes including disability, walking function, cognitive level, and independence of daily living in a cohort of patients with severe traumatic brain injury who received RAGT within the context of multidisciplinary rehabilitation.

MATERIALS AND METHODS

We retrospectively analysed a database that includes patients with severe TBI admitted to an inpatient multidisciplinary rehabilitation programme of the University of Ferrara and who received robot-assisted gait rehabilitation between January 2007 to December 2017. Ethics committee approved the study, but written informed consent was not collectable from all patients since part of them was no longer attending the rehabilitation clinics.

Subjects

The criteria of inclusion for the study were: i) male or female aged over 18; ii) severe or moderate traumatic brain injury (TBI) according to the Glasgow Coma Scale (GCS) [15]. Patients with medical instability, aggressive behaviour and skin lesions were excluded from the use of RAGT. We collected the following demographic and clinical data: age; 2) sex; 3) Glasgow Outcome Scale Extended (GOSE) at admission and discharge; 4) physical limitations (paraosteoarthropathy, limb fractures, spasticity); 5) Level of Cognitive Functioning (LCF) at admission and discharge; 6) motor impairment (right hemiplegia, left hemiplegia, tetraplegia, motor disorders); 7) rehabilitation phase (sub-acute, defined as < 6 months and chronic, defined as > 6 months from the acute event); 8) Functional independence measure (FIM): total score (tFIM), motor subscore (mFIM) and cognitive subscore (cFIM) at admission and discharge; 9) Functional Ambulatory Classification (FAC) at admission and discharge. Moreover, a set of measures related to rehabilitation training protocol were collected, including i) the length of stay in the hospital (LOS), ii) the number of RAGT sessions, iii) the period since TBI event and RAGT training

In our analysis, we focused on the impact of the cognitive level at admission measured by the Level of Cognitive Functioning (LCF) score. It is a scale used to classify cognitive and behavioural disorders caused by TBI. It is structured in eight levels, characterizing the level of cognitive damage from a coma to the full recovery of consciousness [16, 17]. We divided our sample in three main classes according to their LCF level at rehabilitation admission. The first group includes patients with disorders of consciousness that are scored as LCF 2 or 3; the second group is characterized by patients with moderate to severe cognitive and behavioural disorders (LCF score of 4, 5 and 6); the third group presents mild to moderate cognitive and behavioural disorders (LCF score 7 and 8).

Interventions

All patients of the program received robot-assisted gait rehabilitation. RAGT was performed using a robotic exoskeleton system (Lokomat: Hocoma, Switzerland) that can guide hip and knee flexion through braces connecting the patient's legs to the machine. It also provides body weight support (0-100%) through a harness, along with the level of assistance provided by the device. The entire device (including the harness and the motorized exoskeleton orthoses) can be adjusted according to the requirements of the process of treadmill rehabilitation. Motorized exoskeleton orthoses have a biomechanical role, which is to guide movements at the hips and knees that mimic a physiological gait pattern [18]. Parameters are defined based on the functional characteristics of the patient, starting with a 50% reduction in body weight and 100% of the guidance provided by the robot. Over the sessions, adjustments can be made in increments or decrements of 10%. The RAGT session lasts approximately 45 minutes to an hour, including patient preparation. The treadmill speed can vary from 0.1 to 3 km/h [19]. In addition to RAGT, patients benefited from a multidisciplinary rehabilitation programme defined according to the individual's needs (conventional motor rehabilitation, occupational therapy, speech therapy and cognitive rehabilitation).

Multidisciplinary rehabilitation

Rehabilitation is the act of restoring health and function of body and mind. For this purpose, specialized care for a variety of deficiencies due TBI help patients to regain their independence and the better living conditions. Among these treatments defined by conventional rehabilitation, we distinguish occupational therapy, speech therapy, physical and manual rehabilitation, psychological therapy. In addition to RAGT, each patient received multidisciplinary rehabilitation and as individual needed. At the admission, patient was assessed by a rehabilitation team who defined a specific program according to the framework of the international classification of functions of WHO [20, 21]; and at discharge, a clinical evaluation was made to determine the functional improvement of patients.

Statistical analysis

We completed statistical comparisons for each of the demographic and clinical parameters mentioned above. The analysis is based on the Kruskal Wallis rank test for continuous variables and on the Chi Square value for categorical variables. Correlations among variables were tested with the Spearman correlation coefficient (rho) and linear regression models were used to test the impact of cognitive status ad admission on functional recovery. A significance level of $p< 0.05$ was set.

RESULTS

We included 80 participants with TBI: 19 (23.75%) were females (34.55±14.59 years old) and 61 (76.25%) were male (35.82±15.23 years old).The three classes (LCF 2-3, LCF 4-6, LCF 7-8) at admission were comparable for sex, physical limitations (limb fractures, spasticity, paraosteoarthropathy) and motor impairment (right hemiplegia, left hemiplegia, tetraplegia and motor disorders . Conversely, we observed differences across the groups with respect to age (p = 0.024), GCS score (p = 0.005), phase of rehabilitation (p = 0.001) and clinical outcome (FAC, LCF, GOSE, tFIM score, mFIM, cFIM) (p = 0.001). Specifically, the more cognitive impaired group (LCF 2-3) was younger, with a lower GCS score after the TBI, was mostly admitted for rehabilitation in the subacute phase and presented poorer clinical score at admission. Differences among groups were highlighted even considering the time when RAGT was delivered respect to the admission to the rehabilitation (p=0.001). The LCF 2-3 group received RAGT later compared to the other groups during their rehabilitation stay. See Table 1.

INSERT TABLE 1 ABOUT HERE

The analysis showed that participants with a lower cognitive level at admission were mostly in the subacute phase of rehabilitation (p = 0.001) and had the better functional recovery. Specifically, we found an improvement not only with regards to cognition (p = 0.001), but also in walking function (p = 0.037), independence of daily living (p = 0.001), and disability (p = 0.034). These findings were not statistically different in subacute and chronic subgroups, except in relation to cognition (with p = 0.0001). See Table 2.

INSERT TABLE 2 ABOUT HERE

Evidence of greater gains was demonstrated in patients in the subacute rather than chronic rehabilitation phase in all clinical outcomes: LCF (p =0.001); GOSE (p=0.003); FAC (p=0.038) and FIM (p=0.001). See Fig 1.

INSERT FIGURE 1 ABOUT HERE

The level of cognitive function at admission was strongly correlated with the increase in the level of cognitive function at discharge (rho = - 0.83; p = 0.001), moderately with ΔGOSE (rho = - 0.57; p = 0.001), ΔtFIM (rho = - 0.56; p = 0.001), ΔcFIM (rho = - 0.65; p = 0.001) fair with ΔmFIM (rho = - 0.46; p = 0.001) and ΔFAC (rho = - 0.33; p = 0.003). We concluded that the level of cognition at admission can explain the 68.15% of the cognitive improvement (R^2 = 0.68; β = - 0.74, p = 0.001); 32.74% of the disability improvement (R^2 = 0.33; β = - 0.34, p = 0.001); 30% of functional ability improvement (R^2 = 0.3; β = - 9.31, p = 0.001) including 22% motor and 42% cognitive ability, and also responsible for 11% of the improvement in gait (R^2 = 0.11; β = - 0.25, p = 0.003). See Table 3.

Patients with disorders of consciousness have had longer period to recover and longer period to receive the RAGT. More the level of cognition was lower, longer was the period of recover and the period to receive the RAGT (p=0.001). The total number of RAGT sessions did not have influence on the level of consciousness of different patients (p=0.397) (Table 1); and a weak correlation has been observed between RAGT sessions and FIM recovery (rho= 0.2).

INSERT TABLE 3 ABOUT HERE

DISCUSSION

The sequelae resulting from a severe TBI are not only those related to function but also to cognitive, mental and emotional aspects. For this reason, all these elements must be considered by the rehabilitation processes [22-24]. The aim of this work was to produce a comprehensive analysis using demographic and clinical parameters to investigate the impact of the LCF at admission on RAGT and the functional recovery in terms of walking independence, cognitive level, independence of daily living and disability. With the RAGT introduction in rehabilitation as option for delivering a high-intensity for persons affected for severe Brain injury [9, 12, 13], nothing is not clear concerning the level of consciousness of patients with TBI and the RAGT practice.

Following the outcomes observed, patients with disorders of consciousness at admission has a greater improvement at discharge, particularly in cognitive function (p = 0.001). However, we noticed that they were relatively younger (under 30 years old) and age is an important factor in functional recovery during TBI rehabilitation [25-27]. Several studies have shown the ability of young patients to integrate new knowledge and learning skills [5, 27]. Patients of this age class seemed more exposed; they were severely injured during the TBI event. The GCS which is an indicator of the severity of the event and which reflects the violence of the event TBI was more accentuated versus other age groups (p = 0.004) [15]. This aspect justify the large period of these patients in the hospital (LOS) (p=0.001) and the large timing between the event to RAGT training (p=0.001)[28]. This crucial period is necessary to overcome biological and psychological insufficiencies that could negatively condition any progress in the recovery process. Moment especially dedicated to multidisciplinary rehabilitation and in which is highlighted the impact targeted for each patient.

In addition, we observed an important difference in relation to the phase of rehabilitation, as previously highlighted, patients who receive RAGT during a multidisciplinary rehabilitation in the subacute phase of recovery had a more favourable outcome in terms of functional recovery [12]. In our TBI sample, among patients with disorders of consciousness there were more in their first 6 months since injury (75%) than others (41.85 and 7.13%). The consciousness disorder seems not to be an obstacle to the RAGT; but an asset to cognitive relearning especially in young patients in the subacute phase after of course a period of patient stabilization. The high percentage of patients in subacute with disorders of consciousness would have influenced the improvement of clinical parameters especially in this highly impaired population and moderately in the other groups, except for the level of cognition.

However, a slow recovery of consciousness can be detected even in a longer period [29]; these outcomes explain the role of RAGT in the recovery of patients in the subacute phase with varying cognitive levels at admission. Conversely, we did not find differences among groups in chronic TBI. This is explained by the fact that during the rehabilitation, chronic patients experience difficulties in relearning new behaviour; because habits that have already developed are difficult to be replaced [24].

To date, few studies indicate the feasibility of RAGT during rehabilitation of severe TBI with disorders of consciousness [23, 30] further investigations are necessary.

Establishing its positive impact on the functional improvement of patients with severe TBI would be one of the indicators of its usefulness. Cognitive impairments are present in a high proportion of patients following a TBI [2, 3]; conventional treatment combined with RAGT would be a possible solution for improving functional, mental, physical and emotional impairments [31, 32].

In our cohort, the cognitive level at admission influenced the rehabilitation length of stay (LOS) and the time needed to receive RAGT during the multidisciplinary rehabilitation programme. As previously reported, patients with disorders of consciousness need longer period to recover and similarly, a longer period to be able to safely receive the RAGT was necessary [32-35] . Regarding the RAGT intensity parameters, no significant effects on the dose were reported ($p=0.397$), reflecting how the level of cognitive impairment does not modify the number of RAGT sessions received; contrary to what we would have liked on the basis of previous studies in terms of motor functional recovery concerning other types of brain injury [12, 23].

This observational study is limited by the fact of his retrospective aspect firstly, and the fact that we cannot clearly establish a direct cause-effect relationship between RAGT and the cognitive level on functional improvement in patients with severe TBI. Nonetheless, with this work we highlight the feasibility and positive effects of RAGT combined with a multidisciplinary rehabilitation program in these patients, especially those with a disorder of consciousness at admission. Therefore, the level of consciousness could delay the accessibility of severe TBI patients to the RAGT, but, we hypothesize that the patients' consciousness at admission would not interfere in the process of functional recovery as well as in the RAGT training protocol. This study suggests the need for further analysis by prospective and clinical studies to better understand impact cognitive level at admission on functional recovery and RAGT training in patients with severe TBI in multidisciplinary rehabilitation.

CONCLUSION

Robot assisted gait training offers an intensive training and a deeper understanding of its outcomes can help define its clinical applicability. There is some evidence of a change in functional patterns at discharge. We observed, over time, functional improvement principally in cognitive function, which may indicate a broader improvement, although other heterogeneous factors (age, rehabilitation phase) may have influenced recovery. The cognitive level at admission influence the rehabilitation length of stay (LOS) and the time needed to receive RAGT during the multidisciplinary rehabilitation programme. The number of RAGT sessions received is not correlated to the level of cognitive impairment. However the cognitive level at admission without heterogeneous factors seems to be an important indicator of functional recovery. These supports do not exclude the role of RAGT or the impossibility of functional recovery in the rehabilitation of subacute patients with severe TBI with loss of consciousness; contrary, these findings support the multidisciplinary process and the possibilities of functional gain in these patients.

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Table 1. Sample demographics and clinical characteristics

	LCF 2-3 (n=24)	LCF 4-6 (n=42)	LCF 7-8 (n=14)	total (n=80)	p

Age	29.83 (14.77)	37.87 (15.09)	37.21 (12.43)	35.32 (14.84)	0.024
Sex (F/M)	8/16	6/36	5/9	19/61	0.192
GCS score	4.33 (1.73)	5.78 (2.03)	6.78 (2.63)	5.52 (2.22)	0.004
Rehabilitation phase:					0.001
subacute	18	18	1	37	
chronic	6	24	13	43	
Physical limitations:					0.21
limb fractures	8	15	4	27	
spasticity	14	20	6	40	
POA	1	7	2	10	
Motor impairment:					0.546
right hemiplegia	5	7	1	13	
left hemiplegia	4	9	3	16	
tetraplegia	13	22	6	41	
movement disorders	2	4	4	10	
LCF	2.5 (0.51)	5.19 (0.74)	7 (0.00)	4.7 (1.7)	0.001
GOSE	2.37 (0.49)	3.45 (0.8)	4.21 (0.58)	3.26 (0.94)	0.001
FAC	0.17 (0.64)	0.67 (1.12)	2.78 (1.25)	0.88 (1.36)	0.001
tFIM	18.58 (2.04)	41.95 (23.3)	63.71 (17.47)	28.38 (22.74)	0.001
mFIM	13.12 (0.45)	25.33 (18.09)	63.71 (17.47)	28.38 (22.74)	0.001
cFIM	6.04 (3.02)	16.52 (7.66)	31.86 (3.93)	16.06 (10.1)	0.001
Rehab-RAGT (days)	100 (78)	52 (50)	23 (27)	61 (63)	0.001
RAGT (sessions)	17.66 (11.6)	17.13 (9.45)	12.92 (5.61)	16.65 (9.78)	0.397
LOS (days)	184.55 (92.49)	157.44 (99.71)	73.30 (38.30)	153.18 (96.84)	0.001

GCS=Glasgow Coma Scale; POA=paraosteoarthropathy; LCF=Level of Cognitive Functioning; GOSE=Glasgow Outcome Scale Extended; FAC=Functional Ambulatory classification; FIM=Functioning Independence Measure: tFIM (total score), mFIM (motor domain), cFIM (cognitive domain). RAGT=Robot-Assist Gait Training, LOS= Length of Stay

Table 2. Functional improvements according with cognition level at admission and rehabilitation phase.

		LCF 2-3 (n=24)	LCF 4-6 (n=42)	LCF 7-8 (n=14)	total (n=80)	p
DLCF	subacute	3.56 (1.25)	1.29 (0.77)	0 (0.1)	2.35 (1.52)	0.001
	chronic	2 (1.1)	0.58 (0.72)	0 (0)	0.60 (0.9)	0.0018
	Total	3.16 (1.37)	0.88 (0.80)	0.00 (0.00)	1.41 (1.52)	0.001
DGOSE	subacute	2.56 (1.5)	1.6 (0.98)	1 (0.1)	2.1 (1.3)	0.12
	chronic	1.67 (1.51)	0.42 (0.78)	0.23 (0.44)	0.53 (0.93)	0.0495
	Total	2.33 (1.17)	0.92 (0.77)	0.34 (0.47)	1.24 (1.36)	0.034
DFAC	subacute	2.44 (1.5)	1.89 (1.53)	2 (0.1)	2.16 (1.5)	0.47
	chronic	1 (0.6)	0.71 (0.62)	0.92 (0.64)	0.81 (0.63)	0.532
	Total	2.08 (1.47)	1.21 (1.24)	1 (0.68)	1.43 (1.30)	0.037
DtFIM	subacute	57.06 (29.46)	45.11 (25.14)	23 (0.1)	50.32 (27.67)	0.22
	chronic	26.83 (22.78)	9.25 (9.63)	7.31 (8.01)	11.12 (13.14)	0.168
	Total	49.5 (30.54)	24.62 (25.23)	8.43 (8.76)	29.25 (28.76)	0.001
DmFIM	subacute	39 (24.15)	33.83 (21.24)	21 (0.1)	36 (22.39)	0.62
	chronic	18.33 (18.4)	6.17 (6.56)	7 (7.44)	8.12 (9.86)	0.24
	Total	33.83 (24.25)	18.02 (20.27)	8.96 (8.06)	21.01 (21.81)	0.001
DcFIM	subacute	17.94 (7.53)	11.22 (6.86)	2 (0.1)	14.24 (8.04)	0.012
	chronic	8.5 (6.28)	3.08 (4.54)	0.31 (0.63)	3 (4.76)	0.0163
	Total	15.58 (8,24)	6.57 (6.90)	0.43 (0.75)	8.2 (8.56)	0.001

LCF=Level of Cognitive Functioning; GOSE=Glasgow Outcome Scale Extended; FAC=Functional Ambulatory classification; FIM=Functioning Independence Measure: tFIM (total score), mFIM (motor domain), cFIM (cognitive domain).

Table 3. Impact of the cognitive level at admission on functional recovery.

	DF	rho	R-Square	B	t	P
DGOSE	79	- 0.568	0.3274	-0.337	- 6.16	0.000
DFAC	79	- 0.329	0.1081	-0.251	- 3.07	0.003
DLCF	79	- 0.8259	0.6815	- 0.74	- 12.92	0.000
DtFIM	79	- 0.5558	0.3033	- 9.31	- 5.83	0.000
DmFIM	79	- 0.4584	0.2159	-5.956	- 4.63	0.000
DcFIM	79	- 0.652	0.4259	-3.283	-7.61	0.000

R-Square = coefficient of determination; DF = degree of freedom; B= slope of regression; p = probability; rho= coefficient of correlation; rho: coefficient of correlation.

Fig 1. Clinical variation in function of Rehabilitation Phase