ORIGINAL RESEARCH

Bagcilar Med Bull 2022;7(4):319-325
DOI: 10.4274/BMB.galenos.2022.2022-06-055

Clinical Practice Data of Robot-assisted Gait Therapy After Stroke: A Retrospective Study

İnme Sonrası Robot Yardımlı Yürüme Terapisinin Klinik Verileri: Retrospektif Bir Çalışma

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Abstract

Objective: Patients with stroke are often exposed to significant levels of disability resulting in long-term functional limitations. Robot-assisted gait therapy in stroke rehabilitation is a novel modality for improving walking ability and balance. In this retrospective study, we aimed to assess the outcomes of robot-assisted gait training (RAGT) in patients with stroke.

Method: Forty-nine post-stroke patients (mean post-stroke duration 10.82±14.12 months; mean age 57.06±14.73 years; 34 males; 15 females), who underwent RAGT device plus therapeutic exercise (multiple robot-assisted therapy sessions; mean number of sessions 42.37±25.68), were included in this study. The patients' pre- and post-therapy Brunnstrom lower extremity motor staging (Brunnstrom), functional ambulation scale (FAS), Ashworth spasticity scale (Ashworth), and Barthel index (BI) of activities of daily living scores were obtained from medical records and computerized database. Besides, speed and distance improvement were recorded for each patient by RAGT device.

Results: Post-stroke patients experienced statistically significant gains in Brunnstrom, FAS, BI, RAGT device speed and distance outcomes when compared to baseline values ($p<0.05$). There was a moderate positive correlation between RAGT device speed improvement value and baseline Brunnstrom-FAS-BI values (r values=+0.408; +0.371; +0.367 respectively and $p<0.05$). Additionally, there was a moderate correlation between RAGT device speed improvement value and post-therapy Brunnstrom value ($r=+0.353$; $p<0.05$).

Conclusion: Our study results suggest that robot-assisted gait therapy appears to be effective for facilitating returns including motor function, ambulation, and daily living skills in post-stroke patients. This study also demonstrates that the better the functional status of the patient at baseline, the better the improvement in walking speed with the RAGT

Öz

Amaç: İnmeli hastalar, sıklıkla uzun-dönem fonksiyonel kısıtlılık ile sonuçlanan anlamlı düzeyde özürlülüğe maruz kalırlar. İnme rehabilitasyonunda robot yardımlı yürüme yeteneği ve dengenin daha iyi hale getirilmesinde yeni bir yöntemdir. Bu retrospektif çalışmada, inmeli hastalarda robot-yardımlı yürüme terapisinin (RAGT) sonuçlarını değerlendirmeyi amaçladık.

Yöntem: Bu çalışmada, (RAGT) artı terapötik egzersiz (çok sayıda RAGT; ortalama seans sayısı 42,37±25,68) uygulanan kırt dokuz kronik inme hastası (ortalama inme sonrası süre 10,82±14,12 ay; ortalama yaş 57,06±14,73 yıl; 34 erkek; 15 kadın) yer aldı. Hastaların tedavi öncesi ve tedavi sonrası Brunnstrom alt ekstremite motor evreleme değerleri (Brunnstrom), fonksiyonel ambulasyon skalası (FAS), Ashworth spastisite skalası (Ashworth) ve Barthel indeks (BI) günlük yaşam aktivite skorları, medikal kayıtlardan ve bilgisayar veritabanından sağlandı. Bunun yanında, her hasta için hız ve mesafede iyileşme verileri, RAGT cihazı ile kaydedildi.

Bulgular: İnme sonrası RAGT ve egzersiz tedavisi alan hastalarda başlangıç değerlerine kıyasla Brunnstrom, FAS, BI, RAGT cihazı hız ve mesafe ölçüm değerlerinde istatistiksel olarak anlamlı iyileşme gözlendi ($p<0,05$). RAGT cihazı hızda iyileşme değerleri ile başlangıç Brunnstrom-FAS-BI değerleri arasında orta pozitif korelasyon gözlendi (r değerleri sırasıyla +0,408; +0,371; +0,367 ve $p<0,05$). Ek olarak, RAGT cihazı hız iyileşme değerleri ile çalışma sonu Brunnstrom değerleri arasında orta düzeyde bir korelasyon vardı ($r=+0,353$; $p<0,05$).

Sonuç: Çalışma bulgularımız inme sonrası RAGT uygulanmasının inme hastalarında motor fonksiyon, ambulasyon, günlük yaşam aktivitelerinde iyileşmeyi kolaylaştırmada etkili olduğunu göstermiştir. Bu çalışma, aynı zamanda başlangıçta daha iyi fonksiyonel durumu olan inme hastalarında, RAGT cihazı ile yürüme hızında daha fazla iyileşme ve daha

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Cite this article as: Saral İ, Tekeci E, Yayla YT, Çakar E. Clinical Practice Data of Robot-assisted Gait Therapy After Stroke: A Retrospective Study. Bagcilar Med Bull 2022;7(4):319-325

device and the higher the success of the treatment. The authors think that correlation between post-stroke patients' baseline values and output data by RAGT device is an important indicator for prognosis.

Keywords: Activities of daily living, stroke, rehabilitation, robotics

yüksek tedavi başarısı göstermiştir. Yazarlar, inme hastalarının başlangıç değerleri ve RAGT cihazı çıkış verileri arasındaki korelasyonun prognoz açısından önemli bir belirteç olduğunu düşünmektedir.

Anahtar kelimeler: Günlük yaşam aktiviteleri, inme, rehabilitasyon, robot teknolojisi

Introduction

Robot-assisted gait training (RAGT) for regaining and improving walking ability has been developed in order to automate locomotor training of post-stroke patients as a novel neurorehabilitation technique (1-5).

In the area of stroke rehabilitation, balance, gait and neural plasticity improvements are in favor of RAGT (6-19). Independent from stroke etiology-hemorrhagic or ischemic- RAGT therapy could improve the patients' gait in a similar proportion (12). RAGT can be used as a therapeutic approach not only for stroke patients, but also for other neurological patients, such as spinal cord injury and multiple sclerosis patients with promising results (18-21).

RAGT is consistent with the patient-centered therapy according to individual's needs of locomotion (6). Main advantage of RAGT is the quantifiability of locomotor ability of the patient at baseline, after the sessions with a computer screen attached to the device itself. Besides, it lightens the load of the therapist because it involves a programmable task-oriented device (9,13,14).

In the light of the foregoing grounds, in this retrospective study, we aimed to assess functional outcomes of robot-assisted gait therapy in patients with stroke.

Materials and Methods

Study Design and Population

In this retrospective study, forty-nine post-stroke patients (mean post-stroke duration 10.82±14.12 months; mean age 57.06±14.73 years; 34 males; 15 females), who underwent robot-assisted gait therapy (Lokomat® Robotic gait training; Hocoma AG, Zurich, Switzerland) plus therapeutic exercise, were included. Inclusion and exclusion criteria were specified according to the patients' database. Clinical data and functional indexes of seventy patients were assessed from their medical files and computerized database. Patients with conditions that could affect study results such as comorbidities that could affect balance and lower extremity functions (e.g., other neurological diseases, hip or knee replacement, advanced vision and vestibular disorders), poor cognitive skills (mini-mental state examination <24), and poor cooperation were excluded from the study. The patients whose data were included in the study were informed and their consents were obtained. The study was approved by the Local Ethics Committee of Memorial Hospital (approval no: 12.11.2021/007).

Interventions

Lokomat® (Hocoma AG, Zurich, Switzerland) used in the therapy as a robotic device has three parts: Computer-operated robotic exoskeleton, a treadmill and a body-weight support system (5,22,23). It is adjustable to patient's size and form (23). Besides, treatment parameters such as speed, walking distance, walking duration, body weight support, and guidance forces can be defined and recorded by the device (24-28). During therapy sessions, velocity of the treadmill was fixed at 1.5 km/hr and at the beginning, approximately 50% of each subject's body weight was supported. During the following sessions, the bodyweight support was reduced to the minimum as tolerated without substantial knee buckling or toe drag. Guidance force was maintained at 100% during all sessions (10,28). Speed and distance improvement were recorded for each patient.

In the treatment, the therapeutic exercises based on Bobath and Brunnstrom methods were set individually according to the patient's status, consisting of posture, balance, and gait. The procedure focused on gait and balance in order to raise awareness about trunk stability-symmetry and body weight support on the affected leg. Each exercise session was conducted for half an hour.

Clinical Assessment Scales

All patients were clinically assessed by the Brunnstrom motor staging (Brunnstrom) (29), functional ambulation scale (FAS) (30), Ashworth spasticity scale (Ashworth) (31), and Barthel index (BI) of activities of daily living (32) at baseline and at the end of therapy (multiple Lokomat® plus therapeutic exercise sessions; mean number of sessions 42.37±25.68).

The Brunnstrom was used for motor function of the post-stroke survivors. This system contains 6 stages, in which 1 represents "flaccidity" (no movement on the affected lower limb), 2 represents "appearing of spasticity", 3 represents "increase in spasticity", 4 represents "decrease in spasticity", 5 represents "minimal spasticity", and 6 represents "disappearance of spasticity and coordination reappears" (29).

FAS was utilized for ambulation capability. It is a 6-item scale, in which 0 stands for "can't walk", 1 stands for "dependent walk in the form of continuous manual contact", 2 stands for "dependent walk in the form of continuous or intermittent manual contact", 3 stands for "dependent walk in the form of verbal guarding", 4 stands for "independent walk freely on level surfaces only", and 5 stands for independent walk freely on any surface" (30).

The Ashworth was applied for spasticity. This index consists of 5 stages, in which 0 means "no increase in muscle tone", 1 means "slight increase in muscle tone", 2 means "more marked increase in muscle tone through most limb easily flexed", 3 means "considerable increase in muscle tone, passive movement difficult", and 4 means "rigidity of limb in flexion or extension" (31).

BI was used for independency of daily activities. This examination tool has 10 items including feeding, moving from wheelchair, personal cleaning (washing face, combing hair, shaving, cleaning teeth), getting on and off toilet, bathing himself/herself, walking on level surface, ascending and descending stairs, dressing, bowel control, and bladder control. The score for each item is calculated according to independent action or action with help. Higher scores mean more independence (32).

Statistical Analysis

The data were analyzed using GNU Project-PSPP software version 1.6.2 for statistical analysis and Microsoft Excel computer programs. Descriptive statistical methods including frequency, percentage, mean, and standard deviation were used. The Kolmogorov-Smirnov test was applied for testing normality of the data. The Wilcoxon test was used to compare pre- and post-treatment results. The relationship between variables was investigated by the Pearson's correlation coefficient. The results were evaluated at 95% confidence interval, and $p<0.05$ was considered statistically significant.

Results

Forty-nine patients' data (34 males; 15 females; mean age 57.06±14.73 years) were included in this study. As shown in Table 1, the mean time after stroke was 10.82±14.12 months, and participants had either hemorrhagic (34.7%) or ischemic (65.3%) stroke as an etiology. All post-stroke patients had multiple robot-assisted gait therapy sessions, and the mean number of these sessions was 42.37±25.68 (Table 1).

Table 2 shows the results for RAGT speed and distance improvement after therapy. After 42.37±25.68 sessions of RAGT plus therapeutic exercise, the participants had RAGT speed improvement of 23.27±21.25, and RAGT distance improvement of 53.98±77.11 (Table 2).

Table 3 displays motor, functional ambulation, spasticity, and activities of daily living measures (Brunnstrom, FAS, Ashworth, and BI respectively). When compared to the pre-treatment value, all participants had statistically significant improvement in the Brunnstrom, FAS, and BI index ($p=0.0001$ for all, Table 3).

We also analyzed the correlation between RAGT parameters (speed distance improvement) and outcome measures including the Brunnstrom, FAS, Ashworth, and BI. Table 4 and Table 5 describe the Pearson's correlation results. There was a moderate positive correlation between RAGT device speed improvement value and baseline Brunnstrom-FAS-BI values (r values=+0.408; +0.371; +0.367 respectively and $p<0.05$). Additionally, there was a moderate positive correlation between RAGT device speed improvement value

Table 1. Demographic characteristics of post-stroke patients

		n	%
Gender	Male	34	69.4
	Female	15	30.6
Affected side	Right	24	49.0
	Left	25	51.0
Etiology	Hemorrhagic stroke	17	34.7
	Ischemic stroke	32	65.3
		Mean ± SD	**Min-max**
Age (year)		57.06±14.73	23-85
Post-stroke duration (months)		10.82±14.12	1-72
Number of RAGT + therapeutic exercise sessions		42.37±25.68	10-100

SD: Standard deviation. RAGT: Robot-assisted gait therapy

Table 2. RAGT improvement of post-stroke patients

	Mean ± SD	Min-max
RAGT speed improvement	23.27±21.25	-19-71
RAGT distance improvement	53.98±77.11	-94-311

SD: Standard deviation. RAGT: Robot-assisted gait therapy and Brunnstrom value at the end of the therapy (r=+0.353; p<0.05) (Table 4). Besides, a strong positive correlation was observed between post-treatment and pre-treatment values of outcome measures of the participants (Table 5).

Discussion

The findings of this retrospective, cross-sectional clinical trial show that the use of robot-assisted gait therapy elicited significant gains in motor function, ambulation and daily living skills in post-stroke patients. This study also demonstrates that the better the functional status of the patient at baseline, the higher the success of the treatment.

A recent update of a Cochrane database review, published in 2020, analyzed 62 randomized, controlled trials with a total of 2440 post-stroke patients (age range 47-76 years) by comparing the effects of RAGT versus conventional training. The authors concluded that RAGT in combination with therapeutic exercise after stroke was effective for independent walking, and increasing walking speed when compared to conventional training (33). Similar to the results of Cochrane database (33), walking speed of our trial population was ameliorated after robot-assisted gait therapy. Specifically, the mean RAGT speed improvement after the treatment (mean number of treatment sessions 42.37±25.68, minimum: 10 maximum: 100) was 23.27±21.25 in our study.

Table 3. Motor, functional ambulation, spasticity, and activities of daily living measures at baseline and at the end of the therapy

		Baseline		**After RAGT + therapeutic exercise (mean number of sessions= 42.37±25.68)**		
		Mean ± SD	**Min-max**	**Mean ± SD**	**Min-max**	
Brunnstrom lower extremity motor staging (Brunnstrom) (29)		2.33±1.01	1-6	3.22±0.85	1-6	**0.0001**
FAS (30)		1.1±1.16	0-4	2.35±1.25	0-5	**0.0001**
		Count	**%**	**Count**	**%**	
FAS (30)	Score 0- non-functional ambulator (cannot walk)	20	40.82	2	4.08	**0.0001**
	Score 1- dependent ambulator who requires assistance from another person in the form of continuous manual contact	13	26.53	13	26.53	
	Score 2- dependent ambulator who requires assistance from another person in the form of continuous or intermittent manual contact	8	16.33	11	22.45	
	Score 3- dependent ambulator who requires assistance from another person in the form of verbal supervision/guarding	7	14.29	14	28.57	
	Score 4-independent ambulator who can walk freely on level surfaces only	1	2.04	7	14.29	
	Score 5-independent ambulator who can walk freely on any surface			2	4.08	
		Mean ± SD	**Min-max**	**Mean ± SD**	**Min-max**	
Ashworth spasticity scale (Ashworth) lower extremity (31)		1.33±1.36	0-4	1.51±1.08	0-4	0.117
		Count	%	Count	%	
Ashworth spasticity scale (Ashworth) lower extremity (31)	Score 0-no increase in muscle tone	21	42.86	8	16.33	0.117
	Score 1-slight increase in muscle tone	7	14.29	20	40.82	
	Score 2-more marked increase in muscle tone through most limb easily flexed	7	14.29	11	22.45	
	Score 3-considerable increase in muscle tone, passive movement difficult	12	24.49	8	16.33	
	Score 4-limb rigid in flexion or extension	2	4.08	2	4.08	
		Mean ± SD	**Min-max**	**Mean ± SD**	**Min-max**	
BI of activities of daily living (32)		33.78±21.54	5-75	55.71±26.65	5-100	**0.0001**

SD: Standard deviation, RAGT: Robot-assisted gait therapy, FAS: Functional ambulation scale, BI: Barthel index

Table 4. Correlation of RAGT improvement parameters and outcome measures

r*	RAGT speed improvement	RAGT distance improvement
Baseline value of Brunnstrom lower extremity motor staging (Brunnstrom)	**0.408****	0.212
The study end value of Brunnstrom lower extremity motor staging (Brunnstrom)	**0.353****	0.212
Baseline value of FAS	**0.371****	0.220
The study end value of FAS	0.203	0.040
Baseline value of Ashworth spasticity scale (Ashworth)	0.055	-0.090
The study end value of Ashworth spasticity scale (Ashworth)	0.085	-0.085
Baseline value of BI of activities of daily living	**0.367****	0.072
The study end value of BI of activities of daily living	0.267	-0.022

* Pearson correlation, **p<0.05, SD: Standard deviation, RAGT: Robot-assisted gait therapy, FAS: Functional ambulation scale, BI: Barthel index

Table 5. Correlation of the participants

Paired samples correlations	r*
Brunnstrom-baseline & Brunnstrom-therapy end	**0.765****
FAS-baseline & FAS-therapy end	**0.794****
Ashworth-baseline & Ashworth-therapy end	**0.804****
Barthel index-baseline & Barthel index-therapy end	**0.774****

* Pearson correlation, **p<0.05

Neuromuscular and motor impairment in stroke patients can cause muscle weakness, deterioration of motor function, ambulation, and activities of daily living. Besides, the level of impairment in these subjects differs individually (34). In our trial, we found that there was a moderate positive correlation between RAGT device speed improvement value and baseline Brunnstrom-FAS-BI values (r values=+0.408; +0.371; +0.367 respectively and p<0.05). Additionally, there was a moderate correlation between RAGT device speed improvement value and Brunnstrom value at the end of the therapy (r=+0.353; p<0.05). We consider that correlation between post-stroke patients' baseline values and output data by RAGT device is an important indicator for medical prognostication. Also, our study shows that good motor function, ambulation and activity levels of the patients at the beginning of the treatment increase the success of the treatment.

The results reported here support the earlier findings of randomized controlled trials that studied gait ability or independence in activity of daily living by RAGT, and concluded improvements in locomotor milepost in post-stroke patients (2-5,16,26). Mustafaoglu et al. (2) investigated the effects of RAGT in 51 stroke patients. One of the outcomes in their study was BI of activities of daily living. After 6 weeks of therapy, they found that RAGT plus therapeutic exercise (TE) improved BI index significantly when compared to TE alone, or RAGT alone (p<0.016) (2). Moreover, Li et al. (3), published an article about a new RAGT model, called the BEAR-H1 (Shenzhen milebot robot technology). In their multi-center study of 130 stroke patients, they investigated the effectiveness of RAGT. FAS for ambulation was one of the outcomes in the study. They reported that patients had amelioration in FAS score after 4 weeks of rehabilitation (3). Aprile et al. (26) also highlighted the fact that RAGT as a neurorehabilitation tool promoted ambulation (FAS) significantly. Likewise, in the present study, we used the Brunnstrom for motor function (29), FAS for ambulation (30), Ashworth for spasticity (31), and BI for activities of daily living (32). We observed significant improvement after robot-assisted gait therapy in motor, ambulation, and activities of daily living except spasticity (p=0.117 for spasticity index of Ashworth, and p=0.0001 for the rest).

Actually, Morone et al. (35-37) pointed out that baseline ambulation status played an important role to interpret post-stroke patients who might have more gains from RAGT. In their three studies through short-term and long-term follow-up of stroke patients who had RAGT, they reported that when baseline ambulation score was low, the benefit from RAGT would be to a greater extent (35-37). Contrary to these studies, in this study, there was a positive correlation between RAGT device speed improvement value and baseline Brunnstrom-FAS-BI values (r values=+0.408; +0.371; +0.367 respectively and p<0.05). Patients with high functional and ambulation levels had more gains from robot-assisted therapy.

Interestingly, there is a long-term study examining efficaciousness of RAGT versus conventional therapy in stroke during 5-year follow-up (38). In this randomized, controlled study of 63 post-stroke patients, it was concluded that conventional therapy was better than RAGT in terms of walking and endurance. More long-term studies are needed to generate well-defined scientific data.

Study Limitations

Our study has some limitations as well. First, retrospective design and the absence of a control group are major limitations in our study. Second, the number of therapy sessions was different for each patient. Third, the small number of patients can potentially lead to interpret findings cautiously.

Conclusion

In conclusion, our study results showed that robot-assisted gait therapy had a positive effect on motor recovery, ambulation status, and daily living skills in post-stroke patients. Besides, there is positive correlation between robotic speed improvement parameter and baseline outcome measures of therapy including motor function, ambulation, and daily living skills. The authors think that correlation between post-stroke patients' baseline values and output data of speed improvement is an important indicator for prognosis. The better the functional status of the patient at baseline, the higher the success of the treatment. Nonetheless, there is a need for further studies with higher patient numbers to confirm these beneficial effects in post-stroke patients.

Ethics

Ethics Committee Approval: The study is in accordance with the Declaration of Helsinki. The Local Ethics Committee of Memorial Hospital approved this trial protocol at 12/11/2021 with a number of 007.

Informed Consent: Informed consent was obtained from participants participating in the study in this article.

Peer-review: Internally and externally peer-reviewed.

Authorship Contributions

Concept: İ.S., E.Ç., Design: İ.S., Data Collection or Processing: E.T., Y.T.Y., Analysis or Interpretation: İ.S., E.Ç., Drafting Manuscript: İ.S., Y.T.Y., E.T., Critical Revision of Manuscript: E.Ç., Final Approval and Accountability: E.Ç., İ.S., E.T., Y.T.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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