NeuroRehabilitation 34 (2014) 447–453
DOI:10.3233/NRE-141054
IOS Press

Lokomat: A therapeutic chance for patients with chronic hemiplegia

Demet Erdoğan Uçar[a,*], Nurdan Paker[b] and Derya Buğdaycı[b]
[a]*Department of Physical Medicine and Rehabilitation, Dicle University Medical Faculty, Diyarbakir, Turkey*
[b]*Department of Physical Medicine and Rehabilitation, Istanbul Physical Medicine and Rehabilitation Training Hospital, Istanbul, Turkey*

Abstract.
BACKGROUND: Treadmill training with partial body weight support has been suggested as a useful strategy for gait rehabilitation after stroke.
OBJECTIVES: This prospective, randomized, controlled study of gait training tested the feasibility and potential efficacy of using a robotic-assisted gait device, Lokomat, for treadmill training with partial body weight support in subjects with chronic hemiplegia; the device was also compared with conventional home exercise.
METHODS: Twenty-two male ambulatory ischemic or hemorrhagic induced stroke patients with chronic hemiplegia lasting at least 12 months were enrolled in this prospective study. The patients were assigned to either the Lokomat group or the conventional exercise group. The Lokomat group underwent active robotic training for ten sessions (five sessions per week for two weeks). Each session lasted 30 minutes. If a patient missed three consecutive training sessions, he was removed from the study. The Timed Up and Go Test is used to assess mobility and requires both static and dynamic balance. The 10-m Timed Walking Speed Test is designed to determine the patient's overground walking speed. The Mini-Mental State Examination and Hospital Anxiety and Depression Scale were used for mental and psychological evaluation; the Functional Ambulation Categories was used to assess ambulatory status.
RESULTS: Within each eight-week interval, the patients undergoing the Lokomat training demonstrated significantly greater improvement on the Timed Up and Go Test and 10-m Timed Walking Speed Test than those undergoing conventional training.
CONCLUSION: Despite the small number of patients in the study, the present data suggests that the robotic-assisted device, Lokomat, provides innovative possibilities for gait training in chronic hemiplegia rehabilitation by training at higher intensity levels for longer durations than traditional home exercise.

Keywords: Rehabilitation, lokomat, hemiplegia, gait training

1. Introduction

After hemiplegic stroke, treadmill training with partial body weight support and manual assistance to control the trunk and legs has been suggested as a technique to facilitate functional walking [5, 7]. Decrease in muscle strength and motor control, abnormal muscle tone, abnormal sensation, and cognitive and perceptual dysfunction cause gait disturbance in stroke patients. The goals of neurological rehabilitation approaches for individuals who have suffered a stroke are to improve muscle contractile forces and muscle activation, and to increase functional static and dynamic stability while facilitating the relearning of movement patterns.

Conventional gait training typically consists of retraining weight bearing, weight shifting, and balance in static positions of the gait cycle. This is followed by dynamic locomotor tasks [20]. However, abnormalities and gait deviations have been found to persist following these conventional treatment approaches [6]. After hemiplegic stroke, treadmill training with partial body weight support has been suggested as a technique to

*Address for correspondence: Demet Erdoğan Uçar, MD, Dicle University Medical Faculty, Diyarbakir, Turkey. Tel.: +90 4122488001/4578; Fax: +90 4122488111; E-mail: drdemetucar@yahoo.com.

facilitate functional walking. Many severely impaired stroke patients have difficulty bearing their total body weight on the affected leg during the swing phase of gait. It is believed to increase weight bearing on the involved limb, promote symmetry, and facilitate weight shifting, while controlling posture [2].

Rehabilitation therapies that depend on expected plasticity models need to be developed, in order to improve motor abilities and result in long-term progress. New automated locomotion systems have been developed to facilitate step training and to eliminate manual assistance by the physical therapist. One robotic assistive treadmill device, Lokomat, is a powered unit that attaches in parallel to the lower limb segments and moves in unison with the patient, in order to automate locomotion therapy on a treadmill and improve the efficiency of treadmill training. In this system, body weight, walking pace, and shape of the computer program can be controlled. The patient can monitor the status of screen facing the mirror or virtual reality. Belt straps connect the patient, who is unable to walk normally due to hemiparesis, and the robot-assisted system executes walking that is similar to the unaffected side previously.

Herein, we report the results of a randomized clinical trial that alternated two weeks of 20-minute partial body weight treadmill training daily (ten visits, five×per week) with Lokomat at a 1.5 km/h rate compared to conventional home exercise in chronic stroke patients. The aim of our study was to compare the walking ability between the chronic stroke patients who received robotic-assisted gait training and who received traditional home exercise.

2. Methods

2.1. Patients

After approval of the ethics committee in Dicle University (Approval no:146) twenty-two ambulatory ischemic or hemorrhagic induced chronic stroke patients with a disease duration of at least 12 months granted informed consent to participate in the study. The common feature of the patients was chronic hemiplegia. Primary etiology (ischemic or hemorrhagic) of chronic subjects was not an effective factor on functional recovery. Patients were selected among males due to not to be done any bias according to constitutional features between male and female subjects. Self-reported levels of community ambulation were ascertained by Functional Ambulation Categories (FAC) scores [9] Table 1. The patients were assigned to one of two groups, based on a random number list. Patients who met the criteria for study were adult male (>18 years), capability to ambulate 10 meters without personal assistance, and not receiving any other physical therapy. Exclusion criterias were body weight more than 300 pounds (135 kg), FAC score <3 score and not able to walk consistently or independently within the community, cognitive deficits, cardiac disease, spasticity of the lower limbs preventing them from robotic walking, traumatic stroke, intracranial space-occupying lesion-induced strokes, and seizures. Prior to the implementation of the study interventions, all patients were required to have their respective primary care physicians approve their involvement in the study. The rehabilitation program was well tolerated, and no patients withdrew for factors related to the gait training or any undesirable situation.

2.2. Study design

The study was designed as a prospective, randomized, parallel-group, eight-week trial to compare the efficacy of Lokomat treatment (G1) with conventional physical therapy (G2), as well as to determine the most efficient sequence of training phases. Group 1 ($n = 11$) received two weeks of Lokomat training, and Group 2 ($n = 11$) received two weeks of conventional physical therapy. The majority of patients had ischemic stroke. One and 2 hemorrhagic stroke patients were in G1 and G2 respectively. Each patient was evaluated using the 10-m Timed Walking Speed Test (10mTWS) [9] and

Table 1
Functional ambulation category (FAC) scale

0	Patient cannot walk or requires help from 2 or more people
1	Patient requires firm, continuous support from 1 person who helps with carrying weight and with balance
2	Patient requires verbal supervision or assistance to stand with help from 1 person without physical contact
3	Patient requires verbal supervision or assistance to stand with help from 1 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

Fig. 1. A patient undergoing the Lokomat training.

Timed Up and Go Test (TUG) [22]; gait and motor function were assessed at baseline and after two and eight weeks.

2.3. Lokomat

The Lokomat group underwent active robotic training for ten sessions (five sessions per week for two weeks). The duration of each session was 30 minutes. Walking speeds were around 1.5 km/h, with 50% fixed partial body-weight support. The amount of body-weight support was fixed so that the patient could achieve adequate knee extension during stance and toe clearance during swing at 1.5 km/h Fig. 1. If a patient's walking ability improved to the point that he could ambulate at the 1.5 km/h speed under his full body weight, the guidance force of the Lokomat was reduced, effectively decreasing the amount of assistance provided by the device. During Lokomat training, a computer monitor was located in front of the patients. It provided them with biofeedback of their performance.

2.4. Conventional physical therapy

The conventional exercise group received the equivalent additional time of conventional physiotherapy at home as determined by rehabilitation unit physiotherapists. Home exercise procedure focused on gait, in order to raise awareness about trunk stability–symmetry and body weight support on the paretic leg. The programme has been taken five days per week for two weeks included active and passive range of motion, active-assistive exercises, strengthing of the paretic leg and balance training.

2.5. Outcome measures

Each patient was evaluated by one of two rehabilitation specialists who were blinded to the patients' group assignments. In this study, we chose to evaluate walking function using two tests that are common in research of this type, as well as in clinical practice. The 10mTWS test is designed to determine the overground walking speed of an individual by recording the time it takes to traverse a fixed distance. The TUG test is used to assess a person's mobility and requires both static and dynamic balance. It captures the time that a person takes to rise from a chair, walk three meters, turn around, walk back to the chair, and sit down. During the test, patients are expected to wear their regular footwear and use any mobility aids that they would normally require. Scores of ten seconds or less indicate normal mobility, 11–20 seconds are within normal limits for frail elderly and disabled patients, and greater than 20 seconds means the person needs assistance outside and indicates further examination and intervention. All values were recorded on a standard form. The scores were obtained for each patient in both groups at baseline and after two and eight weeks.

2.6. Statistical analysis

Statistical comparisons were performed with SPSS 16.0 for Windows. The Kolmogorov–Smirnov test was used to assess the distribution of continuous variables (10 mTWS and TUG). Nonparametric tests were used to compare both metric and ordinal categorical data. Within-group comparisons of treatment effects relative to baseline were carried out with the Wilcoxon test, and between-group comparisons were performed with the Mann–Whitney U test.

3. Results

At baseline, there were no significant differences in demographic data. The mean ages in G1 and G2 were 56.2 (47–67) and 61.5 (53–74) years, respectively.

The average initial TUG values were 14.2 sec in G1 and 17.1 sec in G2 ($p = 0.142$). The average initial 10mTWS values were 13.3 sec in G1 and 17.5 sec in G2 ($p = 0.059$). The initial values of the groups were correlated.

In the G1 patients, the TUG values after the treatment (12.2 sec) and at eight weeks (11.5 sec) were lower than the baseline ($p = 0.001$, $p < 0.001$). The average 10mTWS values after treatment (10.6 sec) and at eight weeks (9.5 sec) were also lower than the baseline ($p = 0.003$, $p = 0.001$). The TUG and 10mTWS values at eight weeks were significantly lower than after the treatment ($p = 0.026$, $p = 0.01$).

In the G2 patients, the average TUG value after the treatment (16.3 sec) was lower than the baseline score ($p = 0.001$). There was no statistically significant difference in TUG values between eight weeks and baseline ($p = 0.676$). The 10mTWS value after the treatment (16.7 sec) was lower than the baseline score ($p = 0.004$). There was no statistically significant difference in 10mTWS values between eight weeks (17.6 sec) and baseline ($p = 0.341$).

Table 2
Results of the timed up and go test in the groups

	Initial (sn)	After the treatment (sn)	At eight weeks (sn)	*P* value
G1	14.2	12.2	11.5	0.001*/<0.001*
G2	17.1	16.3	17.3	0.001*/0.676
P value	0.142	0.035*	0.011*	

G1 = Lokomat Group. G2 = Exercise Group. * = Statistically significant.

Table 3
Results of the 10-m timed walking speed test in the groups

	Initial (sn)	After the treatment (sn)	At eight weeks (sn)	*P* value
G1	13.3	10.6	9.5	0.003*/0.001*
G2	17.5	16.7	17.6	0.004*/0.341
P value	0.059*	0.007*	<0.001*	

G1 = Lokomat Group. G2 = Exercise Group. * = Statistically significant.

The TUG values after the treatment and at eight weeks were significantly lower in G1 than in G2 ($p = 0.035$, $p = 0.011$) Table 2.

The 10 mTWS values after the treatment and at eight weeks were significantly lower in G1 than in G2 ($p = 0.007$, $p < 0.001$) Table 3.

4. Discussion

Our findings, which compared partial body-weight-supported treadmill training with Lokomat with conventional home exercise, indicate that the positive effects of a robotic walking system on walking speed continue to increase to a greater degree than does home exercise at the end of eight weeks.

Robot-assisted sensorimotor training and task-oriented repetitive movements can improve muscular strength and movement coordination in patients with neurological impairment [5, 7]. Recently, partial body-weight-supported treadmill training for subjects who have suffered a stroke has been suggested for improving the timing and coordination of motor activity of the lower extremities [7]. This method is believed to increase weight bearing on the involved limb, promote symmetry, and facilitate weight shifting, while controlling posture. Subjects who trained using the partial body-weight-supported treadmill made more significant gains than those using the treadmill alone. Results have shown an increase in functional balance, overground walking speed and endurance, and motor recovery in subjects receiving partial body-weight-supported treadmill training, as assessed by the Stroke Rehabilitation Assessment of Movement [19].

Trueblood suggested that partial body-weight-supported treadmill training could be beneficial in normalizing gait and improving balance in patients with chronic stroke [20]. The gait velocity results in our study support this thinking regarding improvements in gait velocity. The rationale for the efficiency of body-weight-supported treadmill training in patients with stroke is that although partial weight support removes some of the biomechanical and equilibrium constraints of bearing a person's full weight, walking movements may be facilitated on the treadmill by activating spinal and supraspinal sensorimotor cortical centers [8]. Indeed, body-weight-supported treadmill training has been shown to be effective in the recovery of gait function diminished by mild and severe hemiparesis due to stroke, even in nonambulatory patients [1, 23].

Paker et al. have also shown effective results with body-weight-supported treadmill training in subjects who are ambulatory but have gait impairments according to parkinson's disease [15]. We also used partial body-weight-supported treadmill training in our study.

Mehrholz reported that robotic gait training might improve independent walking in a Cochrane study [13]. Although our patients were ambulatory, we observed that some of the patients passed through a higher level using assistive devices or orthoses by Lokomat.

A recent study on chronic hemiplegia that studied Lokomat versus overground gait training reported that although there were no significant changes in walking measures between the groups, low extremity motor function and physical functional levels improved over time within both groups [11]. Our study was similar to this study in design and objective, although the groups showed significant benefits, and Lokomat was found to be a superior method.

In another study, Lokomat gait training was compared with conventional exercise in 30 subacute stroke patients who were not ambulatory. No differences were found in walking speed or independence, spasticity, or ability to perform other activities of daily living. It was reported that the Lokomat group increased the duration of single limb support on their paretic leg [10]. In our study, the gains in our ambulatory patients were apparent.

In the study by Peraula, chronic ambulatory patients regained the same walking ability when they received body-weight-supported treadmill training, with or without functional electrical stimulation, compared with an overground walking exercise training program [16]. However, locomotor training on an electromechanical gait trainer plus physiotherapy resulted in significantly better gait ability and daily living competence compared with physiotherapy alone [1, 17]. In physiatry practice, we must not give up conventional techniques, which are less expensive and more feasible than expensive, popular new systems.

In a case study [12] of a patient seven months post-stroke, it was found that substantial improvements in several standard clinical and functional parameters persisted during the followup evaluation at six weeks; in our study, the improvements persisted for eight weeks.

Despite the success of robotic gait therapy, physiotherapy and conventional methods are valued highly and implemented patiently by patients, due to their attainability and cost effectiveness after a stroke [18, 21]. However, which type of physiotherapy should be provided for which patient remains uncertain. A review of ten treatment intervention categories found the strongest evidence for the effectiveness of task-oriented exercise training to restore balance and gait (for example, by practicing moving from sitting to standing) [21]. We also prescribed balance and gait exercises for home therapy for patients in our study.

Earlier benefits of robotic gait treatment were seen in a study by Conesa [4]; eight weeks of intensive rehabilitation including robotic and manual gait training were well tolerated by early stroke patients and associated with significant gains in function. Patients with mid-level gait dysfunction showed the most robust improvement following robotic training. Similarly, we observed the positive effects for eight weeks.

In our study, we also used virtual reality. A virtual walking training program using a real-world video recording has been found to be a valid approach to enhancing gait performance in patients with chronic stroke. In the spatiotemporal gait parameters, greater improvement in velocity and cadence was observed in the experimental group compared with the control group [3]. From a similar perspective, another study found a significantly greater increase in ankle power generation at push-off and greater change in ankle range of motion post-training, as well as in knee range of motion on the affected side during the stance and swing phases [14].

A limitation of this study is the low number of patients. Furthermore, the outcome measurements in this study were not performed by a blinded assessor; therefore, the possibility of a bias exists. The selection of these treatment parameters was based on professional judgment, and they may have been somewhat arbitrary. Lokomat can provide a controlled, consistent level of therapy in many different settings.

5. Conclusions

We conclude that Lokomat might provide functional gains comparable with conventional physical therapy. This study justifies a larger, multicenter trial to investigate the effectiveness of Lokomat in chronic stroke patients. Moreover, the optimal dose of training characteristics (frequency and duration), as well as the precise gait parameters associated with training responsiveness, need further research. Additional evidence is needed to determine whether any type of overground gait training intervention, by itself, is sufficient to affect broad measures of walking function substantially in individuals with chronic stroke.

Acknowledgments

None. No financial biases exist for any author. No support in the form of grants, equipment, or other items received.

Authors' contributions

DU conceived of the study, and participated in its design and coordination and helped to draft the manuscript. NP participated in the design of the study and performed the statistical analysis. DB participated in the sequence alignment. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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