Comparison of high-intensive and low-intensive electromechanical-assisted gait training in stroke patients

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Abstract

Background: This study was conducted to assess the effect of electromechanical-assisted gait training intensity on walking ability in stroke patients.

Methods: The data of two randomized controlled trials (RCTs) under the same study design of evaluation and intervention except intervention time per session were recruited. After matching the inclusion criteria of two RCTs, the experimental groups of each RCT were defined as low-intensive (LI) and high-intensive (HI) group according to the intervention time per session. Primary outcome was the difference of the change in Functional Ambulatory Categories (FAC) between LI and HI gait training. Secondary outcomes were the difference of changes in mobility, walking speed, walking capacity, leg-muscle strength, daily activity, and balance.

Results: The FAC improved after gait training in both groups, but, the changes of FAC were not different between LI and HI groups. The mobility function in LI group improved significantly more than that in HI group. The leg-muscle strength and balance showed the greater improvement in LI group than those in HI group, but did not show statistical significance.

Conclusions: The improvement of walking ability after LI or HI gait training was not different if providing the same total gait training time. By providing the electromechanical gait training intensively, we could shorten the gait training period to improve walking ability.

Trial registration

Name of the registry: Clinical Research Information Service.

Trial registration number: No. KCT0002195(RCT1), No. KCT0002552(RCT2).

Date of registration: 10/04/2016(RCT1), 10/05/2017(RCT2).

URL of the trial registry record: https://cris.nih.go.kr/cris/search

Background

Electromechanical-assisted gait training for stroke patients has been rapidly developed in recent years, and is being used as a new method of rehabilitation [1]. It has been reported in many studies as a treatment option to replace or supplement conventional rehabilitation by means of focused, repetitive, and active motions for stroke patients [2–6]. However, the most effective frequency, duration, and timing of post-stroke robot-assisted gait training is still unresolved [1]. In addition, there were little clinical trials to compare those parameters of gait training because of selection bias and it would be also difficult to perform the randomized controlled trial (RCT) because of patients' preference. Those electromechanical-assisted gait trainings are known to be effective for acute and sub-acute stroke patients [6–8], and meta-analysis suggests that the patients in the first three months after a stroke and those who are not able to walk should seem to benefit the most [7]. However, it is still uncertain what is the most effective intervention time and whether chronic patient needs the long intervention time.

Considering that electromechanical-assisted gait training can provide unlimited, repetitive, and accurate motion, it could be applied for stroke patients who could walk with or without another's assistance, especially those who wish to walk better. Recently, electromechanical-assisted gait training by Exowalk® (HMH Co., Ltd, Incheon, Korea) proved to be as effective as conventional gait training by a physical therapist (Fig. 1). There are two RCTs by Exowalk® which were conducted to investigate the effect of electromechanical-assisted gait training with the same kind of evaluation and the same type of intervention except gait training time per session [9, 10]. The purpose of this study was to assess the effect of electromechanical-assisted gait training intensity on the walking ability in stroke patients.

Methods

Data acquisition

The data for each experimental group of two clinical trials were selected. Both clinical trials were RCTs and conducted with the same kind of evaluation and the same type of gait training intervention except for the intervention time per session.

The first clinical trial (RCT 1) was intended to assess the efficacy of electromechanical-assisted gait training on the walking ability of stroke patients based on ambulatory function, muscle strength, balance, gait speed and capacity. Forty patients with stroke who could stand alone were randomly assigned to the control and experimental groups. The experimental groups underwent gait training assisted by Exowalk® for 30 minutes per session, one session per day, 5 sessions per a week, for a period of 4 weeks, and total gait training time was 600 minutes [9].The second clinical trial (RCT 2) was intended to assess the efficacy of electromechanical-assisted gait training on walking ability of stroke patients who had a stroke over 3 months previously and could walk with or without another's assistance. Forty patients were randomly assigned to the control and experimental groups. The experimental groups underwent gait training assisted by Exowalk® for 60 minutes per session, one session per day, 5 sessions a week, for a period of 2 weeks and total gait training time was 600 minutes [10]. The outcome measures at the end of gait training of 2 weeks were adopted in this study in order to match the total gait training time of 600 minutes [10].

Participant

To minimize the selection bias, we matched the stroke duration and initial functional status of stroke patient in RCT 1 and RCT 2. Inclusion criteria of this study were revised in terms of duration since stroke onset and initial ambulatory function by FAC. The revised inclusion criteria were as follows: (1) ischemic or hemorrhagic stroke confirmed by a brain imaging study; (2) age above 19 years; (3) hemiplegia or hemiparesis confirmed by physical examination, with the ability to walk with help (FAC 2 ~ 5); (4) patients with sufficient cognitive function to control walking speed and direction; (5) stroke with onset more than 3 months previously. The exclusion criteria were the same as in RCT 1 and RCT 2 and were as follows: (1) poor cognition (unable to obey command or a Mini-Mental Status Exam (MMSE) of less than 10); (2) trunk ataxia, inability to stand; (3) severe spasticity (Modified Ashworth Scale (MAS) Grade 3 and 4); (4) severe leg osteoarthritis, inability to walk, and (5) inability to undergo gait training.

The number of subjects in the experimental groups in RCT 1 and RCT 2 were 18 each. Two patients in RCT 1 were excluded because they had stroke less than 3 months previously and their FAC were level 1. Four patients in RCT 2 were excluded because their FAC were level 6 and they could walk independently without help. Thus, the number of subjects included in this study were 30 persons.

Interventions

The experimental group of RCT 1 was allocated to the low-intensity (LI) group with the electromechanical-assisted gait training for 30 minutes per session. The experimental group of RCT 2 was allocated to the high-intensity (HI) group and performed the same intervention for 60 minutes per session.

Measurements And Analyses

Both RCT 1 and RCT 2 had the same outcome measures. The primary outcome was the change of FAC [11]. Secondary outcome were the changes of Rivermead Mobility Index (RMI) [12], 10-meter walk test (10MWT) [13], 6-minute walk test (6MWT) [14], Motricity Index (MI) [15], Berg Balance Scale (BBS) [16], and Modified Barthel Index (MBI) [17]. All assessments were conducted within 1 week before and after gait training. All values are presented as mean and standard deviation (mean ± SD).

Continuous data were compared using the t-test, binary data using a χ^2 test, to compare the data between the LI and HI groups. The significance of changes between pre-gait training and post-gait training in each group was assessed by using a paired Wilcoxon signed-rank test. All statistical analyses were done using SPSS Version 22.0 (SPSS, Chicago, IL, USA). Statistical significance level was set at $p < 0.05$.

Results

Sixteen patients form RCT 1 were included in LI group, and 14 patients were included in HI group in this study. Age in HI group was significantly greater than in LI group (Table 1). Therefore, the data was adjusted by the effects of age using the analysis of covariance (ANCOVA) and least-square mean (LS mean) represents the average covariate value (Table 3).

Table 1
The baseline characteristics of the low-intensity and high-intensity groups

	LI group ($n = 16$) **30min (4 weeks)**	**HI group ($n = 14$)** **60min (2 weeks)**	***p*-value[a]**
Age (years)	46.94 ± 15.61	61.86 ± 11.33	0.006
Gender			0.282
Male, n (%)	10 (62.5%)	6 (42.9%)	
Female, n (%)	6 (37.5%)	8 (57.1%)	
Duration, days	475.31 ± 411.42	511.07 ± 292.91	0.789
Stroke type			0.431
Ischemic, n (%)	8 (50%)	9 (64.3%)	
Hemorrhagic, n (%)	8 (50%)	5 (35.7%)	

[a] T-test and χ^2 test SD

SD, standard deviation; LI, low intensity; HI, high intensity

All outcome measures pre-gait training were not different statistically between LI and HI group ($p > 0.5$). In the LI group, the FAC was 3.19 ± 1.04 pre-gait training and 3.81 ± 1.22 post-gait training, and the FAC improved significantly post-gait training ($p = 0.004$). In the HI group, the FAC was 3.43 ± 1.09 pre-gait training and 3.86 ± 1.17 post-gait training, and the FAC also improved significantly post-gait training ($p = 0.014$). All secondary outcomes in the LI group improved significantly post-gait training. Whereas 10MWT, 6MWT, BBS, and MBI in HI group were improved significantly post-gait training, RMI and MI were not improved significantly (Table 2). The changes of most outcome measures after gait training were not different between LI and HI group. However, the change of RMI in LI was significantly greater than that in HI group (Table 3).

Table 2
The outcome measures before and after gait training

	LI group (*n* = 16) 30min (4 weeks)			HI group (*n* = 14) 60min (2 weeks)		
	Pre- gait training	**Post- gait training**	p- **value**	**Pre- gait training**	**Post- gait training**	p- **value**
FAC	3.19 ± 1.04	3.8 ± 1.22	0.004	3.43 ± 1.09	3.86 ± 1.17	0.014
RMI	5.38 ± 2.39	6.87 ± 2.60	0.003	7.71 ± 3.73	7.93 ± 3.47	0.317
10MWT	0.47 ± 0.83	0.72 ± 1.56	0.002	0.38 ± 0.28	0.43 ± 0.29	0.010
6MWT	89.87 ± 68.64	108.34 ± 74.10	0.017	105.07 ± 90.65	125.00 ± 94.68	0.006
MI	44.44 ± 14.27	51.25 ± 12.94	0.003	54.29 ± 18.97	56.36 ± 17.57	0.068
BBS	28.38 ± 13.52	34.8 ± 13.85	0.001	31.79 ± 18.81	35.21 ± 18.25	0.002
MBI	58.19 ± 16.98	64.56 ± 17.34	0.001	63.86 ± 20.59	75.21 ± 14.55	0.012

P-value by Wilcoxon signed-rank test between pre-gait training and post-gait training

Numbers are mean ± standard deviation

FAC, Functional Ambulation Categories; RMI, Rivermead Mobility Index; 10MWT, 10-meter walk test; 6MWT, 6-minute walk test; MI, Motricity Index; BBS, Berg Balance Scale; MBI, Modified Barthel Index

Table 3
The change of outcome measures before and after gait training and the difference of values between the low-intensity and high-intensity group

	LI group (n = 16) 30min (4 weeks)		HI group (n = 14) 60min (2 weeks)		p-value
	Mean ± SD	LS mean ± SE	Mean ± SD	LS mean ± SE	
FAC	0.63 ± 0.61	0.68 ± 0.15	0.43 ± 0.51	0.36 ± 0.16	0.200
RMI	1.50 ± 1.41	1.54 ± 0.30	0.36 ± 0.63	0.30 ± 0.32	0.015
10MWT	0.24 ± 0.73	0.27 ± 0.14	0.56 ± 0.51	0.02 ± 0.15	0.284
6MWT	20.96 ± 27.31	18.28 ± 6.26	21.35 ± 18.39	24.41 ± 6.75	0.537
MI	6.81 ± 6.55	6.70 ± 1.63	2.07 ± 5.32	2.19 ± 1.76	0.090
BBS	6.50 ± 4.41	6.39 ± 1.06	3.43 ± 3.20	3.55 ± 1.14	0.099
MBI	6.38 ± 4.89	11.36 ± 18.73	8.52 ± 3.42	8.89 ± 3.69	0.946

P-value by the analysis of covariance of age between LI and HI groups

Numbers are mean ± standard deviation

LS mean, least square mean; SE, standard error; FAC, Functional Ambulation Categories; RMI, Rivermead Mobility Index; 10MWT, 10-meter walk test; 6MWT, 6-minute walk test; MI, Motricity Index; BBS, Berg Balance Scale; MBI, Modified Barthel Index.

Discussion

This study was conducted to assess the effect of electromechanical-assisted gait training intensity on walking ability in stroke patients. The intensity of gait training was defined according to the intervention time per session because electromechanical-assisted gait training could provide unlimited repetition and most accurate motion. Thus, the data of two RCTs which had the same study design of intervention and evaluation except intervention time per session were recruited; 30 minutes for 4 weeks (RCT 1) and 60 minutes for 2 weeks (RCT 2). Because the improvement of walking ability in RCT 1 and RCT 2 was not different after matching the inclusion criteria and total intervention time, we suggested that intensive gait training could shorten the gait training period.

Mehrholz et al. [7] investigated 36 trials of electromechanical-assisted gait training involving 1472 participants and concluded that electromechanical-assisted gait training in combination with physiotherapy increased the odds of participants becoming independent in walking, but did not significantly increase their walking velocity or walking capacity. However, they interpreted the results with caution, because some trials investigated people who were independent in walking at the start of the study, and they found differences between the trials in terms of the duration of intervention and frequency. It is still uncertain what is the most effective frequency and intervention time of electromechanical-assisted gait training. This study hypothesized that training intensity might be based on the number of repetitions during walking movement, and high-intensive gait training could improve walking ability more than low-intensive gait training. However, the improvements of walking ability by high and low intensive gait training were not different if providing the same total intervention time.

Most studies applied the intervention time for around 30 minutes per day or session [18–22] because it is a tolerable exercise time for stroke patients. However, a few studies tried the intervention time for 60 minutes per session [21, 22] and it was tolerable for chronic stroke patients who could walk with or without help. Bang and Shin [21] reported that chronic stroke patients who had robot-assisted gait training for 60 minutes a day, 5 days a week, for 4 weeks, showed better walking abilities and balance than those who had treadmill gait training. However, Stein et al. reported that robotic therapy for ambulatory stroke patients with chronic hemiparesis using a robotic knee brace resulted in only modest functional benefits that were comparable to those from a group exercise intervention, although they did the robot therapy for 60 minutes a day, 3 days a week, for 6 weeks [22]. We also tried intensive 60-minute gait training to get a better result by increasing the intervention time per session and found that the 60-minute electromechanical-assisted gait training improved ambulatory function as much as the physical therapist-assisted gait training although the improvements did not meet the minimally clinically important difference [10].

Stroke patients who could walk with another’s assistance (FAC 2, 3) or requiring help (FAC 4, 5) were included in this study. Chronic stroke patients who could walk with help participated actively in RCT 2 because they wanted walk well. And they could tolerate 60-minute gait training and eagerly wanted to obviate the need for a cane or another’s assistance. This study had new inclusion criteria of the chronic patients who had stroke duration over 3 months and those who could walk help. The patients of FAC 6 in RTC 2 who could walk independently were excluded, because they could walk without help and did not expect further improvement of FAC. Although RCT 2 had provided additional gait training of 2 weeks for the consented patients, the outcome measures at the end of additional gait training were not different from those at the end of initial gait training of 2 weeks [10]. Thus, this study adopted the outcome measures at the end of gait training of 2 weeks in the RCT 2.

We intended to find out whether we could shorten the gait training period if providing the electromechanical-assisted gait training intensively, because Exowalk® could provide unlimited repetition and most accurate motion. This study found the same improvement of walking ability after 2 or 4 weeks of gait training if providing the same total intervention time. However, the improvement of mobility by low-intensive gait training of 4 weeks was better compared to high-intensive gait training of 2 weeks. The improvement of muscle strength and balance were also significant in low-intensive gait training, but did not reach the statistical significance ($p = 0.090$, $p = 0.99$). Because the patients in this study were old and chronic hemiplegia or hemiparesis, the long period of gait training intervention might be beneficial for improving mobility. RMI is a test to assess mobility based on 15 items ranging from turning over in bed to running. It includes both walking ability and daily activity. While walking velocity and capacity improved in both LI and HI groups, the daily activities in the LI group improved more than those in HI group. Because the daily activities of lying, sitting and bathing needed muscle strength and balance, the change of RMI in LI group was greater than that in HI group.

Limitations

This study was conducted by combining two separate RCTs to evaluate the effect of gait training intensity on walking ability instead of designing a prospective study because it was difficult to assign the different walking capacity patients to different intervention time randomly. Although two RCTs had the same protocol of intervention and evaluation, they had different inclusion criteria and were vulnerable to selection bias.

No power calculations were performed because sample data for this study from two previous trials. We need to follow the carry over effect by evaluating outcome measures at 4 weeks in the HI group, because we shortened the intervention period by intensive gait training and expected the improvement to be lasted.

Conclusions

We could expect the same improvement of walking ability after LI or HI gait training, if we provided the same total gait training time. We could shorten the gait training period by providing the gait training intensively and we could improve the mobility function by providing the long period of gait training in stroke patients.

Abbreviations

MMSE
Mini-Mental State Examination
FAC
Functional Ambulation Categories
RMI
Rivermead Mobility Index
10MWT
10meter walk test
6MWT
6minute walk test
MI
Motricity Index
BBS
Berg Balance Scale
MBI

Modified Barthel Index.

Declarations

Ethics approval and consent to participate

RCT 1 and RCT 2 were approved by ethics committee at the Dongguk University Ilsan Hospital's Institutional Review Board (approve No. 2016-64, 2017-18) and registered at the clinical research information service (CRIS Registration No. KCT0002195, KCT0002552). All participant signed informed consent forms after the detail explanation of each study.

Consent for publish

Not applicable.

Availability of data and materials

The data presented in this study are available on reasonable request from the corresponding author.

Competing interests

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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Author contributions

All authors contributed to the study and preparation of the manuscript. BSK have made substantial contributions to conception and design. CSY drafting and revising the manuscript, acquisition of data. YGN participated in the statistical analysis and interpretation of data. All authors have read and agreed to the published version of the manuscript.

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Figures

Figure 1

Exowalk®, HMH Co., Ltd: **A** anterior view. **B** lateral view

Supplementary Files

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