

Effects of Functional Electrical Stimulation During Gait Training on Gait, Balance, and Lower Extremity Function in Chronic Stroke Patients

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| Abstract |

PURPOSE: To examine the effects of functional electrical stimulation during gait training on the gait, balance, and lower extremity function of chronic stroke patients.

METHODS: A total of 20 subjects diagnosed with chronic stroke were randomly divided into experimental group that performed functional electrical stimulation during gait training, and a control group applied with only functional electrical stimulation, with 10 subjects in each group.

RESULTS: In the Berg Balance Scale, the experimental group ranged from 19.80 ± 4.93 to 24.30 ± 6.63 and the control group ranged from 39.40 ± 12.72 to 40.10 ± 13.18 , which showed significant differences ($p < .05$), and there was a significant difference between the groups ($p < .05$). In 10 Meter Walk Test, the experimental group ranged from 28.70 ± 4.03 to 26.42 ± 3.56 , which showed significant differences ($p < .05$), and there was a significant difference between the

groups ($p > .05$). In Fugl-Meyer Assessment Scale-Lower extremity, the experimental group ranged from 22.70 ± 4.49 to 25.30 ± 4.39 and the control group ranged from 21.10 ± 5.34 to 25.30 ± 4.49 , which showed significant differences ($p < .05$), and there was no significant difference between the groups ($p > .05$).

CONCLUSION: Functional electrical stimulation during gait training may be suggested as an effective program for improving gait, balance, and lower extremity function of stroke patients. Therefore, functional electrical stimulation during gait may be recommended as part of the rehabilitation program for chronic stroke patients.

Key Words: Balance, Stroke, Walking

I. Introduction

Stroke refers to a cerebrovascular disease in which blood supply to the brain is cut off or bleeding occurs in brain tissue, resulting in blood supply obstacles of cerebrovascular disease [1]. Stroke patients suffer from sensory impairment and decreased balance ability. In the standing posture, the paralyzed lower limb shared less weight, resulting in an

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asymmetric standing posture. This leads to many limitations in daily life, such as walking and moving [2,3,4].

The recovery of walking function after the onset of stroke is the greatest challenge faced by patients. So improve the ability to walk is one of the important goals of treatment of independence in daily life [5], walking ability is closely related to lower limb function.

In the rehabilitation programs related to balance and walking for stroke patients, functional electrical stimulation is a common treatment method. Walking can be improved by strengthening muscle strength and muscle reeducation [6]. It also increases energy efficiency while stroke patients walk [7]. Functional electrical stimulation during gait training and partial weight support has significant effects on the walking and balance of stroke patients [8].

According to previous studies, when functional electrical stimulation is not treated alone in a passive state, combined with other active movements, the therapeutic effect decreases, necessitating the inclusion of other combinations of active movements [9]. However, because passive treatment mainly occurs in clinical practice, patients' concentration is frequently reduced. The decrease in concentration makes it difficult to expect cerebral stimulation due to lack of motivation and patient participation in physical therapy [10].

Although there are many researches showing that functional electrical stimulation treatment has a positive effect on the walking ability of stroke patients, there are no studies on the effects of gait training combined with functional electrical stimulation treatment on lower limb function in chronic stroke patients. Therefore, this study aims to investigate the effect of functional electrical stimulation during gait training on gait, balance, and lower extremity function in chronic stroke patients.

II. Methods

1. Participants

This study was conducted on chronic stroke patients

diagnosed with stroke through magnetic resonance imaging (MRI) and computed tomography (CT) at 00 rehabilitation hospital in BUK-GU of Daegu city. All subjects were fully explained the methodology and purpose of the study prior to participating in the study. And the patients voluntarily agreed to participate in the study. A pilot study was conducted to determine the number of subjects for the research, and the G-Power program was used to calculate the sample size based on the pilot study data. Twenty patients who met the selection criteria of the study subjects were randomly placed in each group through drawing lots, and the results were analyzed after statistical processing with the collected data of 20 patients who completed the study. Functional electrical stimulation therapy as a control group included 10 chronic stroke patients, functional electrical stimulation during gait training as an experimental group included 10 chronic stroke patients.

The criteria for selecting subjects are as follows. Those who have been at least 6 months after the onset of stroke, those with a Korean version of mini mental status examination (K-MMSE) score more than 24 points [11], those who have no orthopedic disease related to walking, those who have no abnormal symptom in electrical stimulation, those who have a modified Ashworth scale (MAS) lower limb stiffness of grade 1 or 2 [12], those who have a functional ambulation category (FAC) score higher than 2 points [13], and those who can perform independent walking of 10M or more [14]. The criteria for excluding subjects from the study are as follows. Those who have cognitive impairment and mental dysfunction, those stroke patients also have other conditions that affect their balance.

2. Experimental Procedure

This study was conducted after approval by the Bioethics Committee of Daegu University (1040621-202301-HR-013). In order to select the subjects of this study, 20 patients who were admitted to 00 rehabilitation hospital in BUK-GU

of Daegu city. The subjects were asked to understand the purpose of the experiment and explain the experiment process, and the patients who agreed to receive the training were trained. General characteristics such as gender, weight, height, and age were investigated through medical treatment before training. The experimental group performed functional electrical stimulation during gait training and the control group performed only functional electrical stimulation for 15 minutes a day, 5 times a week, for a total of 20 times for 4 weeks. All subjects in each group performed the conventional central neurodevelopmental treatment (NDT), such as muscle strengthening exercise, stretching exercise, and walking exercise for 30 minutes. All subjects performed the Berg balance scale (BBS) to evaluate the change in balance ability before and after the experiment, and a 10Meter walking test (10MWT) to evaluate the change in walking ability. In order to evaluate the change in lower limb function, the Fugl-Meyer assessment scale-lower extremity (FM-LE) was performed. All interventions were administered by a physical therapist with at least three years of clinical experience, taking into account the individual functional level of each subject.

3. Intervention

1) Functional Electrical Stimulation Device

The functional electrical stimulation therapy device used SERA (Double Walking, GOS, Korea) to affix the active electrode to stimulate the common fibular nerve. Reference electrodes are placed in the tibialis anterior muscle to stimulate the muscles in the ankle and toes that are controlled by the common fibular nerve. The waveform of the functional electrical stimulation was a two-way square wave, the frequency was 80 Hz, the pulse width was set 300 μ s. The intensity of the electrical stimulation is set to be significant muscle contractions happen when electrical stimulation is applied to the patient [15,16]. Electrical stimulation of the tibialis anterior muscle starts

from the point at which the ball of the foot leaves the ground until the heel touches the ground. This process adds up to during the swing phase of dorsiflexion of the ankle joint. The electrical stimulation be applied in this process.

4. Outcome Measures

1) Berg Balance Scale (BBS)

The berg balance scale was developed for the balanced assessment of the elderly, and it is an evaluation tool that has been recognized for its validity for diseases such as stroke and traumatic brain injury [17,18]. The berg balance scale is divided into three categories of sitting, standing, and posture change, is a total of 56 points, applying a minimum of 0 to a maximum of 4 points. The measurement tool is a high validity and reliability, with intra-rater reliability $r = 0.99$ and inter-rater reliability $r = 0.98$ [18].

2) 10Meter Walk Test (10MWT)

Mark a distance of 10Meter on the treatment room floor for assess walking time, and to measure the average walking speed. The average walking speed is measured for Average walking speed in the middle 6 meters. The 2 meters for speed up and the 2 meters speed reduction was subtracted. After going through an exercise process, the researchers asked the subjects to walk twice at the highest possible speed in a safe state to record the fastest walking speed [19].

The reliability of the test-retest method of this test is high Intra-class correlation coefficient $t = 0.95-0.96$ [20].

3) Fugl-Meyer assessment scale-lower extremity (FM-LE)

Fugl-Meyer assessment scale-lower extremity It is designed to evaluate motor function, balance, sensation, and joint function in hemiplegic patients after stroke. It is also used clinically to determine the degree of disease, assess the level of exercise recovery, and establish a treatment plan [21].

The lower extremities are subdivided into hip, knee,

ankle, coordination ability, etc. [22]. Each part of the evaluation scale has three evaluation criteria with different scores (0 point: none perform, 1 point: partially perform, 2 points: fully perform). The Fugl-Meyer assessment scale-lower extremity exercise function was used in this study, and the reliability of this evaluation tool was reported, with intra-rater reliability $r = .94$ and inter-rater reliability $r = .99$ [22,23,24].

4. Data Analysis

For the statistical analysis of this study, SPSS version 23.0 for window software program was used, and descriptive statistics analysis were used for the general characteristics of the subject. All data were tested for normality using the Shapiro-Wilk test, and analyzed using a parametric test accordingly. A paired t-test was performed to find out the changes before and after the intervention in the group, and an independent t-test was performed for comparison between groups. The statistical significance level (α) was set to .05.

III. Results

Data were analyzed for a total of 20 patients who participated in this study. The measurements for all evaluations are presented in the table. There was no significant difference between groups on the general characteristics of the subjects who participated in this study ($p > .05$) (Table 1). As a result of this experiment, there was a significant difference in the BBS before and after intervention in both the experimental group and the control group ($p < .05$). There was also a significant difference in comparison between groups ($p < .05$) (Table 2).

In the 10MWT, there was a significant difference before and after intervention in the experimental group ($p < .05$), but there was no significant difference before and after intervention in the control group ($p > .05$). There was a significant difference in comparison between groups ($p < .05$) (Table 3).

In the FM-LE, there were significant differences before and after intervention in both the experimental group and

Table 1. General characteristics of the subjects(n = 35)

Characteristic	EG (n = 10)	CG (n = 10)	p
Gender (male/female)	6/4	8/2	.949
Age (year)	59.90 ± 8.86	62.70 ± 17.40	.782
Height (cm)	162.80 ± 7.25	168.20 ± 9.98	.251
Weight (kg)	63.60 ± 13.23	62.80 ± 13.39	.974

Mean ± SD: Mean ± standard deviation, EG: functional electrical stimulation therapy training during walking group, CG: Functional electrical stimulation therapy group

Table 2. Changes of BBS score between two groups (M ± SD) (unit: score)

BBS	Pre	Post	t	p	Effect size(d)	Change rate(%)
EG	19.80 ± 4.93	24.30 ± 6.63	-3.14	.012 *	.77	22.72
CG	39.40 ± 12.72	40.10 ± 13.18	-0.77	.460 *	.05	1.77
t	7.458	-3.385				
p	.001	.005 *				

Mean ± SD: Mean ± standard deviation, EG: functional electrical stimulation therapy training during walking group, CG: Functional electrical stimulation therapy group, BBS: Berg balance scale * $p < .05$

Table 3. Changes of 10MWT score between two groups (M ± SD) (unit: sec)

10MWT	Pre	Post	t	p	Effect size(d)	Change rate(%)
EG	28.70 ± 4.03	26.42 ± 3.56	3.74	.005 *	.59	7.94
CG	24.96 ± 2.08	23.06 ± 3.47	1.31	.220	.66	7.61
t	2.983	2.134				
p	.018	.047 *				

Mean ± SD: Mean ± standard deviation, EG: functional electrical stimulation therapy training during walking group, CG: Functional electrical stimulation therapy group, 10MWT: 10Meter walking test *p < .05

Table 4. Changes of FM-LE score between two groups (M ± SD) (unit: score)

FM-LE	Pre	Post	t	p	Effect size(d)	Change rate(%)
EG	22.70 ± 4.49	25.30 ± 4.39	-4.20	.002 *	.58	11.45
CG	21.10 ± 5.34	25.30 ± 4.49	-8.20	.000 *	.85	19.90
t	1.432	.000				
p	.478	1.000				

Mean ± SD: Mean ± standard deviation, EG: functional electrical stimulation therapy training during walking group, CG: Functional electrical stimulation therapy group, FM-LE: Fugl-Meyer assessment scale-lower extremity *p < .05

the control group (p < .05). There was no significant difference in comparison between groups (p > .05) (Table 4).

IV. Discussion

The purpose of this study was to find out the changes in gait, balance, and lower extremity function of the experimental group that applied functional electrical stimulation during gait training for 4 weeks and the control group that applied only functional electrical stimulation therapy in chronic stroke patients over 6 months. Both the control group and the experimental group performed the basic central neurodevelopmental treatment (NDT) for 30 minutes, and the experimental group performed functional electrical stimulation during gait training for 15 minutes a day, 5 times a week, for a total of 20 times for 4 weeks.

In the comparison of the BBS to measure the balance

ability in this study, there was a significant difference between the experimental group and the control group before and after the intervention, and there was also a significant difference in the comparison of changes between the experimental group and the control group. These results are because, when applied with functional electrical stimulation therapy, it can have a positive effect on muscle strength and cross-sectional increase of muscles in stroke patients [16,25], And functional electrical stimulation therapy applied in tibialis anterior muscles can increase the functional range of motion of the ankle joint and generate efficient movement of the knee and ankle joints [16,26,37]. In summary, it is believed that the functional electrical stimulation treatment applied to the tibialis anterior muscles It can increase the strength of the tibialis anterior muscle, increasing the stability of the ankle, and increasing the range of motion of the ankle joint to enable efficient movement, thereby improving the functional

movement control ability, and ultimately improving the balance ability. The significant difference in the comparison of the amount of change between the experimental group and the control group is that the tibialis anterior muscle is a muscle that plays a role in controlling the ankle joint [28,29], especially when walking, and since it is a muscle that is highly activated when walking [30,31], it is thought that functional electrical stimulation training during walking therapy improvement of the adjustment ability of the tibialis anterior muscle, resulting in a greater improvement in the balance ability in the experimental group. These results are consistent with previous studies reporting that there was a significant improvement in the balance ability of stroke patients after functional electrical stimulation during gait training [32].

In the comparison of the 10MWT to measure the walking ability in this study, the difference in the experimental group before and after intervention was statistically significant ($p < .05$), but no significant difference was found before and after the intervention in the control group ($p < .05$), and a significant difference was found in the comparison of change value in the experimental group and the control group ($p < .05$). The significant improvement was only seen in the experimental group that applied functional electrical stimulation during gait training. The result suggests that functional electrical stimulation of the tibialis anterior muscle alone cannot improve walking ability without gait training. This is consistent with previous studies that reported a significant effect on improving walking ability after functional electrical stimulation during gait training in 495 stroke patients over 6 months [33].

In the comparison of the FM-LE to measure the lower limb function ability in this study, significant difference between the experimental group and the control group before and after the intervention ($p < .05$), but there was no significant difference in the comparison of the amount of change between the experimental group and the control group ($p > .05$). In the result of walking and balance ability,

there were significant difference in the amount of change between the experimental group and control group, FM-LE for measuring lower limb function, did not show a significant difference in the amount of change between the experimental group and control group. The reason for this is that the FM-LE is a measure used to evaluate the overall function of the lower limb, including sensory and joint function assessments [34], so it is considered that it did not affect the difference in the amount of change between the two groups after intervention

The limitations of this study, That first is the effect of walking training for 4 weeks was evaluated, and the long-term treatment effect could not be judged, and the follow-up test was not conducted. Second, the quality of life and daily life behavior were not evaluated. And third, it is difficult to generalize the results of this study to all stroke patients by conducting an experiment with a small number of subjects of 20. In future studies, it is thought that higher quality research results can be derived if these limitations are supplemented.

V. Conclusion

The purpose of this study was to compare the group that applied FES during walking with the group that applied only FES. The BBS was used to evaluate balance ability. And the 10MWT used to evaluate walking ability. the change value in the experimental group and control group was a statistically significant difference both of evaluations. but the change value was no statistically significant difference between the experimental group and control group in the FM-LE used to evaluate the lower extremity function. These results suggest that functional electrical stimulation during gait training have a positive effect on the balance and gait of chronic stroke patients, and functional electrical stimulation during gait training can be suggested as a rehabilitation program for chronic stroke patients.

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