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Abstract

Objective: To determine whether a single trial of interferential current therapy (ICT) can immediately alleviate spasticity and improve balance and gait performance in patients with chronic stroke.

Design: Randomized, placebo-controlled clinical trial.

Setting: Inpatient rehabilitation in a local center.

Subjects: A total of 42 adult patients with chronic stroke with plantar flexor spasticity of the lower limb.

Intervention: The ICT group received a single 60-minute ICT stimulation of the gastrocnemius in conjunction with air-pump massage. In the placebo-ICT group, electrodes were placed and air-pump massage performed without electrical stimulation.

Main measures: After a single ICT application, spasticity was measured immediately using the Modified Ashworth Scale (MAS), and balance and functional gait performance were assessed using the following clinical tools: Functional Reach Test (FRT), Berg Balance Scale (BBS), Timed Up and Go Test (TUG), and 10-m Walk Test (10MWT).

Results: Gastrocnemius spasticity significantly decreased in the ICT group than in the placebo-ICT group (MAS: ICT vs placebo-ICT: 1.55 ± 0.76 vs 0.40 ± 0.50). The ICT group showed significantly greater improvement in balance and gait abilities than the placebo-ICT group (FRT: 2.62 ± 1.21 vs 0.61 ± 1.34 , BBS: 1.75 ± 1.52 vs 0.40 ± 0.88 , TUG: 6.07 ± 6.11 vs 1.68 ± 2.39 , 10MWT: 7.02 ± 7.02 vs 1.96 ± 3.13). Spasticity correlated significantly with balance and gait abilities ($P < 0.05$).

Conclusion: A single trial of ICT is a useful intervention for immediately improving spasticity, balance, and gait abilities in chronic stroke patients, but not for long-term effects. Further study on the effects of repeated ICT is needed.

Keywords

Stroke, interferential current therapy (ICT), spasticity, balance, gait

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Introduction

Stroke, a leading cause of disability and mortality in modern society, results from ischemic or hemorrhagic damage in the brain.¹ Symptoms generally reflect sensory and motor dysfunction that are associated with asymmetry of postural control and accompanied by balance and gait disorders.² Among these symptoms, spasticity is the chief cause of motor impairments, including balance and gait ability.³ Thus, restoration of motor function and spasticity is one of the major goals of stroke rehabilitation.

Although surgical and pharmacological interventions have been used to manage motor function impairments and spasticity, they are often accompanied by side effects such as pain, loss of sensory and motor functions, and gastrointestinal symptoms.^{4,5} Recently, interventions using electrical stimulation, such as transcutaneous electrical nerve stimulation and functional electrical stimulation, have been used to manage sensory and motor functions in stroke patients.⁶⁻⁸ Electrical stimulation applied to the somatosensory area effectively increased reorganization of the motor cortex, including the primary motor cortex and dorsal premotor cortex.⁹ Also, intervention using electrical stimulation is easy to apply, safe to use, and have fewer side effects relative to other interventions.

Interferential current therapy (ICT) is an electrical stimulation method that has been commonly used in clinics to treat several types of pain.¹⁰ Recently, it has been reported that this intervention can improve symptoms and life quality in irritable bowel syndrome patients and prevent muscle atrophy.^{11,12} We hypothesized that interferential current therapy would improve motor function and spasticity in stroke patients as other electrical stimulation methods.

Therefore, the aim of this study was to investigate the effect of interferential current therapy on spasticity, balance, and walking ability in chronic stroke patients.

Methods

Participants

This study was a randomized, single-blind, placebo-controlled clinical trial. One research

assistant screened the subjects on the basis of the inclusion and exclusion criteria as follows: participants were included in the study if they (1) had experienced stroke onset ≥ 6 months, (2) scored ≥ 21 on the Mini-Mental State Examination¹³, (3) had calf spasticity (≥ 2 on the Modified Ashworth Scale), and (4) could stand independently without an assistive device for >10 minutes.⁶ Participants with orthopedic disorders, circulatory insufficiency, hemi-neglect, psychiatric disorders or dementia, skin problems, and previous experience with interferential current stimulation were excluded. All participants received written and verbal descriptions of the study procedures and signed consent forms indicating agreement to participate in the study. All experimental procedures were approved by the Gachon University Institutional Review Board.

Experimental procedure

Inpatients with chronic stroke at local rehabilitation centers were recruited through a bulletin board post describing the study purpose. There were 46 volunteers, four of whom were excluded on the basis of inclusion and exclusion criteria. To eliminate potential experimental bias, 42 inpatients were randomly assigned to ICT group and placebo-ICT group using random allocation software.¹⁴ This process was conducted by one blinded experimental assistant until there were no significant differences between two groups for any variable. G-Power 3.1 (University of Dusseldorf, Dusseldorf, Germany) was used to calculate the sample size. The power and alpha level were set to 0.080 and 0.5, respectively. The effect size was set to 0.8.⁶ The results indicated that at least 21 subjects were required in each group.

Measurements for all participants in both groups were obtained both immediately before and one hour after therapeutic intervention under a blinded condition (Figure 1). Prior to intervention, both groups participated for 30 minutes in a standard rehabilitation program based on the Bobath technique. Electrical stimulation was applied for 60 minutes in a single session using an interferential current therapy device (IF-7P; ITO CO., Japan).

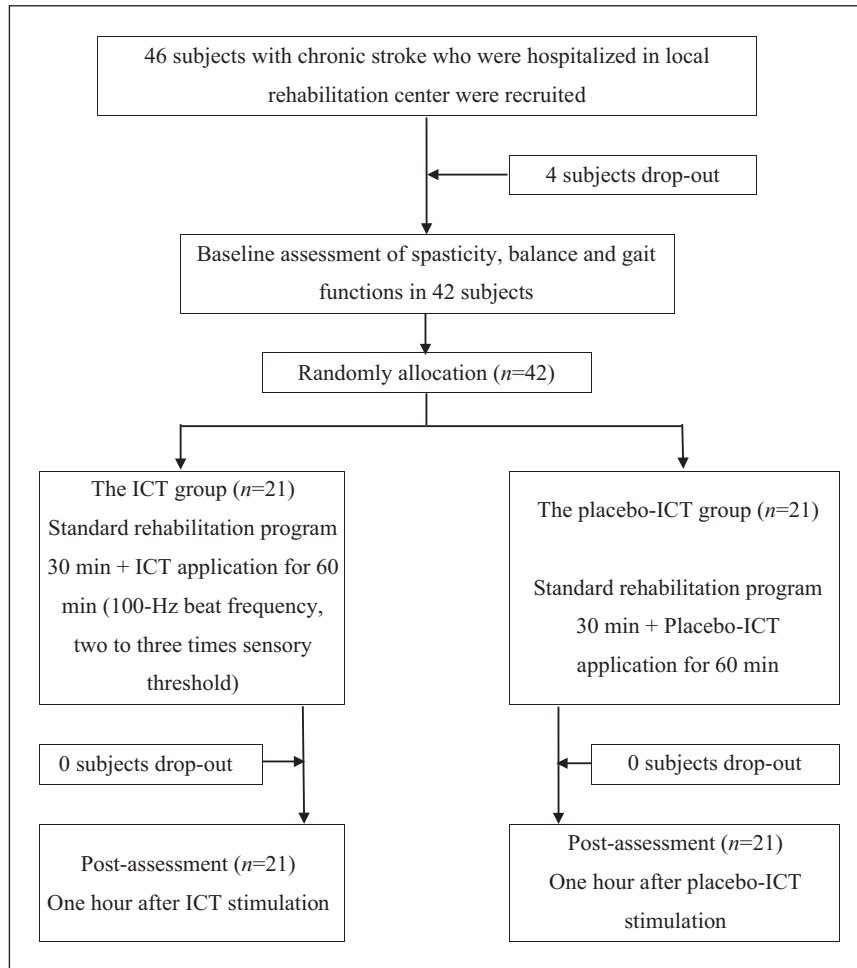


Figure 1. Flow chart of present study.

Interferential current therapy was applied via four electrodes in a quadrant setting; electrodes were applied to the muscle belly surfaces of the ipsilateral medial and lateral gastrocnemius fibers. Interferential current therapy device produces a modulated rectangular waveform with a 50% duty cycle and a resultant 100-Hz beat frequency (4000-Hz on one set of leads and 4100-Hz on the other). To assess each subject's sensory threshold, the intensity of electrical stimulation was increased until the subject felt stimulation.¹⁵ We applied the sensory threshold to each subject in the ICT group 2-3 times; for the placebo-ICT, electrodes were attached, but no electrical stimulation was applied.

Outcome measurements

Gastrocnemius spasticity was scored according to the Modified Ashworth Scale ($r = 0.90$).¹⁶ The scale comprises 6 stages (0, 1, 2, 3, 4, and 5) to represent the resistance or tone felt by the examiner when moving the limb from maximal ankle plantar flexion to dorsiflexion. To test dynamic postural balance, the Functional Reach Test and Berg Balance Scale were used. The reliability of the Functional Reach Test and the Berg Balance Scale in stroke patients are 0.98 and 0.97, respectively.^{17,18} Gait function was tested using the Timed Up and Go Test ($r = 0.95$), which assesses the

Table 1. General subject characteristics.

	ICT group (n=21)	Placebo-ICT group (n=21)
Gender (male/female)	15/6	14/7
Age (years)	54.40 ± 12.05	53.85 ± 12.44
Height (cm)	163.53 ± 6.63	163.00 ± 6.14
Weight (kg)	60.73 ± 9.00	62.61 ± 10.10
Etiology (infarction/haemorrhage)	14/6	15/5
Onset-time (months)	15.05 ± 4.86	13.85 ± 5.08
MMSE (score)	26.10 ± 1.74	25.80 ± 2.12

Values are expressed as mean ± SD. MMSE, Mini-Mental State Examination.

performance of sequential motor tasks.¹⁹ Gait speed, which is important for safe mobility, was tested using the 10-m Walk Test ($r = 0.92$). Each measurement for balance and gait was repeated three times, and the results were averaged.²⁰

Data analysis

Statistical analyses were performed using SPSS 15.0. The normality of each data distribution was confirmed using the Shapiro-Wilk test. For the Modified Ashworth Scale and Berg Balance Scale, the Mann-Whitney U-test and the Wilcoxon signed-rank test were used to compare intragroup and intergroup differences, respectively. For the Functional Reach Test, Timed Up and Go Test and 10-m Walk Test, and the paired and independent t-tests were performed to examine within-group and between-group differences, respectively. The significance level was set at $P < 0.05$.

Results

Figure 1 illustrates the study flow diagram. At baseline, there were no significant differences between groups for gender, age, height, weight, etiology, onset-time, and Mini-Mental State Examination score (Table 1, $P > 0.05$).

Changes in spasticity after the application of interferential current therapy or placebo-interferential current therapy are shown in Table 2. Although both groups showed significant reductions in spasticity after therapeutic intervention, the magnitude of the decrease was significantly greater

in the ICT group (41%) than in the placebo-ICT group (11%) ($P < 0.05$).

The balance ability showed greater improvement in the ICT group than in the placebo-ICT group (19% vs. 11% on the Functional Reach Test and 5% vs. 1% on the Berg Balance Scale, $P < 0.05$).

According to the Timed Up and Go Test, gait abilities decreased significantly after interferential current therapy (19%) and placebo-ICT (6%). In addition, the results of the 10-m Walk Test improved by 16% in the ICT group and by 4% in the placebo-ICT group. Thus, interferential current therapy application significantly improved balance and gait abilities compared to the placebo ICT (Table 2, $P < 0.05$).

Discussion

This study demonstrated that interferential current therapy application to the gastrocnemius effectively alleviated spasticity and improved balance and gait abilities in chronic stroke patients.

Spasticity was reduced approximately 41% after intervention. Similar to our results, the application of transcutaneous electrical nerve stimulation to acupuncture points or spastic muscles reduced spasticity by approximately 9–30%.^{8,21} However, the extent to which anti-spastic effects can be compared between our study and those in previous studies is limited by differences in applied parameter variables such as the attachment site, intensity, and applied duration. In our previous study, transcutaneous electrical nerve stimulation application to the calf using the same applied

Table 2. Changes in spasticity, balance ability, and gait function after the application of interferential current therapy or placebo- interferential current therapy.

		ICT group	Placebo-ICT group	P
MAS score	Pretest	3.80 ± 0.89	3.70 ± 0.73	0.701
	Posttest	2.25 ± 0.72	3.30 ± 0.66	
	Post – Pre	1.55 ± 0.76 ^{*,#}	0.40 ± 0.50 [#]	< 0.001
	P	< 0.001	0.002	
FRT (cm)	Pretest	13.76 ± 3.37	14.08 ± 2.94	0.758
	Posttest	16.38 ± 2.66	15.69 ± 2.60	
	Post – Pre	2.62 ± 1.21 ^{*,#}	0.61 ± 1.34	< 0.001
	P	< 0.001	0.058	
BBS score	Pretest	36.15 ± 5.98	37.06 ± 5.61	0.543
	Posttest	37.90 ± 5.65	37.44 ± 5.62	
	Post – Pre	1.75 ± 1.52 ^{*,#}	0.40 ± 0.88	< 0.001
	P	< 0.001	0.057	
TUG (sec)	Pretest	32.04 ± 23.22	27.94 ± 14.45	0.506
	Posttest	25.97 ± 18.83	26.26 ± 13.30	
	Post – Pre	6.07 ± 6.11 ^{*,#}	1.68 ± 2.39 [#]	0.005
	P	< 0.001	0.006	
10MWT (sec)	Pretest	44.75 ± 18.40	45.93 ± 13.22	0.819
	Posttest	37.74 ± 15.70	43.96 ± 12.04	
	Post – Pre	7.02 ± 7.02 ^{*,#}	1.96 ± 3.13 [#]	0.007
	P	< 0.001	0.011	

Values are expressed as mean ± SD. MAS, Modified Ashworth Scale; FRT, Functional Reach Test; BBS, Berg Balance Scale; TUG, Timed Up and Go; 10MWT, 10 meter walk test. ^{*}represents a significant difference versus the placebo-ICT group and [#]indicates a significant difference from the pretest value.

parameter variables showed an anti-spastic effect of approximately 29%.⁶ This infers that interferential current therapy is more effective than transcutaneous electrical nerve stimulation for alleviating spasticity in stroke.

Interferential current therapy generates a 100-Hz interference wave between two medium-frequency currents across the skin surface. The maximal therapeutic effect is generated in deep tissue within the treatment area.¹⁰ In a previous report, the true interferential current therapy, in which current interference is generated in tissue, had more pronounced effects on deep tissue than premodulated interferential current therapy did, in which an interference current was elicited only in the machine.¹⁵ Thus, we assume that interferential current therapy stimulated the muscle more directly.

The placebo-ICT group also showed an anti-spastic effect of approximately 11%. We assume

this is due to the air-pump massage with intervention. Massaging the gastrocnemius decreases the H-reflex amplitude, which may reduce motor neuron excitability and in turn, decrease spasticity.²² Moreover, both groups received the standard rehabilitation, which is the pivotal clinical method for spasticity management and motor rehabilitation. Thus, the standard rehabilitation per se likely improves spasticity.

Inhibitory neurotransmitters such as GABA and opioid agonists can exert anti-spastic effects by inducing neurotransmitter inhibition of the presynaptic terminals.²³ High-frequency (100-Hz) electrical stimulation results in inhibitory neurotransmitter release in the spinal cord.²⁴ Our intervention produced a resultant beat frequency of 100-Hz into tissues; therefore, this intervention would be expected to increase endogenous levels of inhibitory neurotransmitters and might induce similar effects to anti-spastic drugs.

Electrical stimulation improves balance ability because cutaneous and proprioceptive sensory inputs contribute to perception of a vertical posture in patients with hemispatial neglect.²⁵ Stimulation of the calves helps to retain or control the posture, including an upright stance.²⁶ Similarly, our results showed that interferential current therapy application to the calves reduced postural imbalance following stroke approximately 20%. Various studies have shown that somatosensory stimulation elicits and changes motor cortex excitability.²⁷ The resulting excitability of the corticospinal tract increases the movement of the center of gravity.²⁸ Thus, ICT stimulation may influence balance ability by affecting sensory stimulation input to the nervous system.

In previous studies, electrical stimulation intervention has been shown to be effective in improving mobility or walking ability in approximately 6.5–10.4% stroke patients.^{7,8} Similarly, interferential current therapy stimulation significantly enhanced gait ability about 16% in the present study. Damaged proprioception in muscles and joints of the ipsilateral-side is the chief cause of gait impairment in stroke patients.²⁹ As outlined above, in the context of triggering proprioception, it can be assumed that the enhancement of proprioceptive inputs to muscle proprioceptors by interferential current therapy stimulation may improve gait function. In addition, gait is a balance-related movement in stroke patients.⁸ Our study showed that interferential current therapy stimulation increased balance ability, which may be an important factor for improving gait function.

Spasticity disturbs a patient's voluntary movement and motor function;³⁰ therefore, it should be managed to achieve balance and gait performance. Free movement of ankle dorsiflexion is the chief factor determining gait speed,³¹ and ankle position is also important for maintaining balance during ambulation and gait.³² In our results, interferential current therapy stimulation of the calves decreased spasticity in the plantar flexor muscles. In addition, spasticity correlated significantly with balance (Modified Ashworth Scale and Functional Reach Test: $r = 0.802$, $P < 0.001$) and gait (Modified Ashworth Scale and Timed Up and Go Test: $r =$

0.575 , $P < 0.001$; Modified Ashworth Scale and 10-m Walk Test: $r = 0.696$, $P < 0.001$). Thus, we assume that improvements in balance and gait ability resulted from relative increases in dorsiflexor performance by reducing spasticity using interferential current therapy stimulation.

This study has some limitations. First, we provide only short-term effects of interferential current therapy. In addition, although not described, the anti-spastic effects and improvements in balance and gait functions following intervention are not maintained for more than one day. Second, some participants felt uncomfortable in the prone posture for interferential current therapy application; hence, posture management should also be considered. Third, this study is a relatively small sample size. Thus, future studies will include long-term effects of repeated interferential current therapy application on spasticity, balance, and gait functions with a large number of patients using various measurement tools. Additional research is needed to identify the most effective parameters of interferential current therapy application for alleviating spasticity and improving balance and gait function.

Clinical message

- A single application of interferential current therapy to spastic muscle immediately alleviated spasticity and improved balance and gait abilities in patients with chronic stroke.

Conflict of interest

The authors declare that there is no conflict of interest.

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