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The Effect of Robot-Assisted Gait Training with Rhythmic Auditory Stimulation on Lower Limb Function, Balance and Gait in Hemiplegic Stroke Patients

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Objective: This study compared the effect of lower limb function, balance and gait between robot-assisted gait training with and without rhythmic auditory stimulation (RAS) in hemiplegic stroke patients.

Design: Randomized controlled trial.

Methods: Thirty-one strokepatients were randomly divided to robot-assisted gait training with RAS (RGTR) group (n = 15) and control group (n = 16). Both groups undergone robot-assisted gait training and conservative exercise therapy for 30 minutes each, five times a week, for 4 weeks. The RGTR group additionally received RAS during the robot-assisted gait training. To analyze the effect of the training, Lower limb function was Fugl-Meyer assessment lower extremity, balance ability was stability index and Berg balance scale, and Gait ability was using gait parameters obtained using a gait analyzer (Zebris FDM-T system) were measured.

Results: According to the training, the RGTR group showed of increased significantly in lower limb function, balance, and gait ability in the within-group before-after difference ($p < 0.05$).In the between-group difference comparison, the RGTR group were significantly better improvements in the Berg balance scale of balance ability and among gait ability, all gait parameters except for cadence than the control group ($p < 0.05$).

Conclusions: Thisstudy offer that robot-assisted gait training with RAS in performed together with conservative exercise therapy is an effective training method of improving balance and gait ability in hemiplegic stroke patients.

Key Words: Stroke, Robotics, Acoustic stimulation, Posture balance, Gait

Introduction

Stroke patients typically rely on residual muscles for movement control and gait, which are affected by changes in muscle response due to muscle weakness and stiffness [1]. Compared to healthy adults' gait parameters, stroke patients exhibit abnormal gait patterns, involving decreased cadence, prolonged the paretic side swing phase time, prolonged the non-paretic side stance phase time, and asymmetry in step length [2]. As a result, 75% of stroke patients experience gait impairments, which limit their ability to live independently and reduce their quality of life [3].

Robot-assisted gait training during task-oriented training can provide customized training programs for patients by guiding lower limb movements according to pre-input physiological gait patterns [4]. Additionally, repetitive training with physiological gait patterns has been shown to promote symmetrical muscle activation and induce neuroplasticity changes in the brain to

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enhance motor learning [5]. However, Pennycott et al. [6] suggested that the passive assistance provided by robotic assistive devices can reduce the patient's manual effort, leading to decreased lower limb muscle activity.

To address this issue, rhythmic auditory stimulation (RAS), inducing active movement, can be considered as auditory cues in a steady rhythm, which immediately causes synchronization between the motor and perceptual areas of the brain. Additionally, it enhances the spatiotemporal component of movement by temporally structuring movement patterns, which can more efficiently retrain normal rhythmic movement patterns [7]. According to Roerdink et al. [8], gait training using RAS improves joint angles, flexibility, and spatiotemporal changes in stroke patients. Furthermore, Park et al. [9] reported that treadmill gait training with RAS improved walking speed and step length on the affected side. Based on these previous studies, providing gait training using RAS to stroke patients may be effective in improving gait ability. However, most studies have focused on treadmill and ground gait training, and research involving robot-assisted gait training with RAS is lacking.

Therefore, this study the goal is to investigate changes in lower limb function, balance, and gait ability in hemiplegic strokepatients when RAS was provided during robot-assisted gait training.

Methods

Participants

This study targeted hospitalized stroke patients at M Rehabilitation Hospital located in Yeongdeungpo-gu, Seoul. The sample size required for the research was decided with the G*Power software(ver. 3.1.9; University Düsseldorf, Germany). The effect size was set to 1.13, power to 80%, and significance level to 0.05 based on previous studies. Calculation resulted in a sample size of 28 participants, and considering a 10% dropout rate, 32 participants were recruited [10]. Selection criteria were individuals who have been diagnosed with a stroke and have been affected for more than 6 months but less than 1 year, a functional ambulation category score of 2 or higher, and a Korean version of mini-mental state examination to over 24 score. Exclusion criteria were individuals with limitations in hip joint motion or range of motion, individuals with neurological conditions other than stroke, and those with visual or hearing impairments. This study was conducted from June 07, 2023 to August 20, 2023, and before the experiment, signed the research consent from were obtained to all participants who met the selection criteria. This research was approval from the Institutional review board at the MyungjiChunhye rehabilitation hospital (approval no: MJCHIRB-2023-01).

Procedure

A total of 32 participants were selected in the trial and randomly assigned into robot-assisted gait training with RAS (RGTR) group (n = 16) and control (n = 16) groups using an Excel random number table after selecting. Both groups training five times a week for 4weeks.The RGTR group undergoneRGTR and conservative exercise therapy for 30 minutes each for 60 minutes, and the control group undergone robot-assisted gait training excluding RAS, and conservative exercise therapy for 30 minutes each, for 60 minutes. During the experiment, one participant dropped out of the RGTR group due to early discharge. Therefore, in the RGTR group the final test was conducted on 15 patients, and in the control group on the 16 patients (Figure 1).

Intervention method

Robot–assisted gait device

A robotic-assisted gait device (Morning Walk®, Curexo, Seoul, Korea) was used for RGTR and robot-assisted gait training without RAS (Figure 2). Morning Walk® is a system that comprises of an end-effector robot-assisted gait and a seated weight-bearing system. It has a saddle that makes boarding easy and safe, and allows for precise control of the participant's ankle movements. This enables movement of the ankle, knee, and pelvis in response to the trajectory of the footrest, which supports overall body movement control. The cadence can be adjusted from 4 to 70 steps/min, and the step length can be adjusted

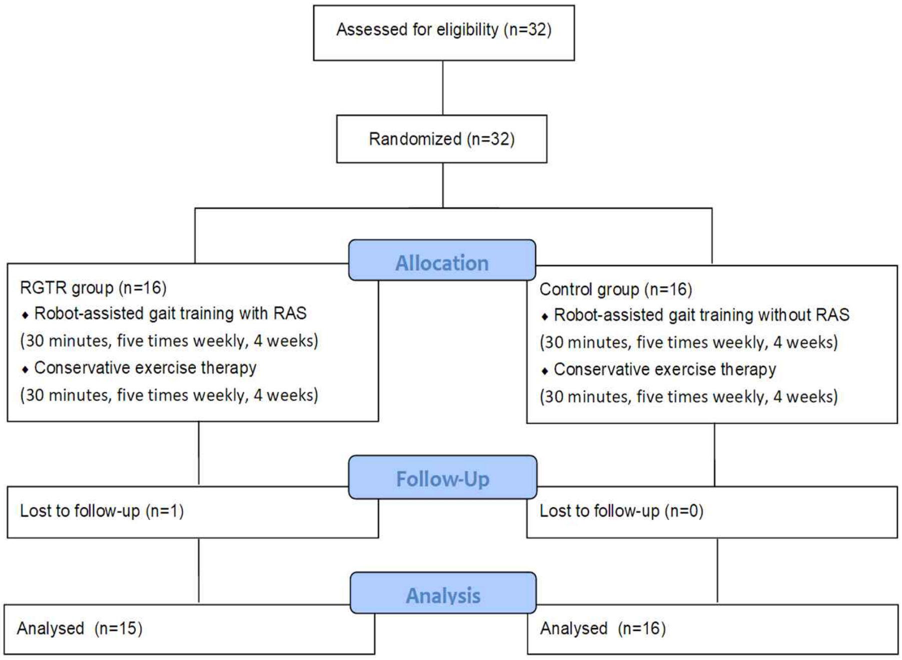

Figure 1. Flow diagram of the study

Figure 2. Robot-assisted gait device

from 30 to 55 cm [11].

Robot–assisted gait training with RAS (RGTR)

RAS was provided during the initial grounding phase of the paretic lower limb using the metronome feature of the Morning Walk® equipment program [12]. The tempo of the RAS was set 10% faster than the participant's cadence, which was measured using the gait analyzer before the experiment [8]. In addition, the robot-assisted gait training to be combined with RAS was modified and supplemented based on the intervention method presented in the previous study by Kim et al. [11]. As such, participants began with a cadence 10% faster than the pre-measured frequency and a step length of 30–35 cm, which could be adjusted according to the participants' functional level.

Robot–assisted gait training

The control group undergone training under identical conditions as the RGTR group. However, to prevent the provision of RAS, the power to the speaker connected to the Morning Walk® device was turned off during robot-assisted gait training.

Conservative exercise therapy

Both groups received conservative exercise therapy from a physical therapist with at least 5 years of clinical experience. conservative exercise therapy is composed of range of motion exercises, muscle strengthening exercises, balance exercises, and gait exercises.

Outcome measure

Lower limbfunction

In this study, the Fugl–Meyer assessment lower extremity (FMA-LE) was employed for assessing lower limb function.FMA-LE consists a total of 17 items, with a minimum of 0 and a maximum of 2 for each item, for a total 34 points. Scores of 17 or less indicate severe disability, 18–22 as marked disability, 23–28 indicate moderate disability, 29–33 indicate mild disability, and 34 is considered normal [13]. FMA-LE has an inter-rater reliabilities(0.95) are high[14].

Balance ability

1. Stability index

In this study, stability index (SI) was measured using Tetraxdevice (Sunlight Medical Ltd., Ramat Gan, Israel) to assess static balance ability(Figure 3). SI indicates the stability of the center of gravity by measuring the change in vertical pressure applied to the four force plates. A higher score on the SI indicates greater fluctuations in the center of gravity. The data collected through Tetrax was analyzed using an in-house program linked to the equipment. Tetrax has an intra-rater (0.88) and test–retest (0.89) reliabilities are high [15].

2. Berg balance scale

In this study, the Berg balance scale (BBS) was employed for the evaluation of dynamic balance ability.This scale consists a total of 14 items, with a minimum of 0 and a maximum of 4 for each item, for a total of 56 points, with higher scores means a better degree of balance ability. According to Berg et al. [16], patients scoring 45 or less were at increased risk of falls. BBS has an intra-rater (0.98) and inter-rater (0.97) reliabilities are high [17].

Gaitability

In this study, a gait analyzer (Zebris FDM-T System, Zebris Medica GmbH, Isny, Germany) was employed for measuring the participants' gait ability (Figure 4). The gait analyzer used in the study is a system that integrates a pressure measurement sensor and a treadmill, which collects pressure signals as the

Figure 3. Device of Tetrax for measure static balance ability

Figure 4. Device of Zebris FDM-T for measure gait ability

participant walks on the treadmill and automatically analyzes 14 spatiotemporal parameters related to gait through Zebris FDM-T software (version 1.18.44) [18]. In this study measured, among 14 gait parameters, velocity, cadence, stride time, step length of paretic side, stride length, and single limb support of paretic side.Zebris FDM-T has an intraclass correlation coefficient (0.96) are high [19].

Dataanalysis

All data analyses were enforced using SPSS (ver. 25, SPSS Inc., Chicago, IL, USA). After confirming the normal distribution of the all variable values using the Shapiro-Wilk test, chi-square test and independent t-test were enforced to confirm the homogeneity between-groups. The paired t-test was enforced to compare pre- and post- results within-group through the training program, and the independent t-test was enforced to compare results between-groups. The significance threshold for all statistical data was set at p-value < 0.05.

Results

The participants general characteristics were as follows (Table 1).

Both groups significantly improved their FMA-LE scores after training ($p < 0.05$). However, no significant disparities were revealed in the between-group comparison. SI for balance ability significantly increased only in the RGTR group after training ($p < 0.05$). BBS significantly increased after training for both groups ($p < 0.05$), and the between-group difference comparison revealed a significant enhancement in the RGTR group relative to the control group ($p < 0.05$) (Table 2).

Velocity and cadence for gait ability both groups significantly improved after training ($p < 0.05$). However, in the between-group difference comparison, only velocity exhibited a significantly enhanced in the RGTR group relative to the control group ($p < 0.05$).A significant enhancement in stride time was appeared exclusively in the RGTR group after training ($p < 0.05$), and the between-group difference comparison revealed a significant enhancement in the RGTR group relative to the control group ($p < 0.05$).Step length of paretic side and stride length significantly increased after training in both the RGTR and control groups ($p < 0.05$), and the between-group difference comparison revealed a significant enhancement in the RGTR group relative to the control group ($p < 0.05$).A significant enhancement in single limb support of paretic side were found only in the RGTR group after training ($p < 0.05$), and the between-group difference comparison the RGTR group exhibited a significantly enhanced in the relative to the control group ($p < 0.05$)(Table 3).

Table 1. General characteristics of theparticipants (n=31)

	RGTR group(n=15)	Control group(n=16)	χ^2/t(p)
Sex(male/female)	8/7	9/7	0.158(0.876)
Stroketype(infarction/hemorrhage)	10/5	11/5	0.120(0.905)
Areas of paralysis (right/left)	7/8	9/7	0.518(0.608)
Age (years)	55.00(14.15)	60.68(11.21)	-1.244(0.223)
Height (cm)	164.40(9.22)	163.50(10.44)	0.254(0.802)
Weight (kg)	66.33(11.16)	68.18(11.39)	-0.457(0.651)
Time since onset (month)	8.40(1.63)	8.81(1.72)	-0.682(0.500)
MMSE-K (score)	27.60(1.72)	27.31(1.70)	0.467(0.644)
FAC (score)	2.47(0.64)	2.38(0.62)	0.405(0.688)

Values are presented as number or mean (standard deviation).

RGTR: robot-assisted gait training with RAS, RAS: rhythmic auditory stimulation, MMSE-K: mini-mental state examination-Korean version, FAC: functional ambulation category.

Table 2. Comparison of lower limb function and balance ability (n=31)

	RGTR group(n=15)		Control group(n=16)	
	Pre-test	Post-test	Pre-test	Post-test
Lower limb function				
FMA-LE(score)	18.07(4.75)	21.60(3.94)**	18.68(5.10)	21.18(3.42)*
Balance ability				
SI(score)	20.73(4.69)	18.54(3.15)*	21.29(4.34)	19.72(4.62)
BBS(score)	39.40(5.87)	43.93(3.59)**†	38.43(5.46)	40.81(4.76)**

Values are presented as number or mean(standard deviation).

RGTR: robot-assisted gait training with RAS, RAS: rhythmic auditory stimulation, FMA-LE: Fugl-Meyer assessment lower extremity, SI: stability index, BBS: Berg balance scale.

Between the group($^{\dagger}p<0.05$), within the group($^{*}p<0.05$, $^{**}p<0.01$).

Table 3. Comparison of gait ability

	RGTR group(n=15)		Control group(n=16)	
	Pre-test	Post-test	Pre-test	Post-test
Gait ability				
Gait velocity(m/s)	0.36(0.07)	0.44(0.08)**†	0.34(0.07)	0.38(0.06)*
Cadence(step/min)	65.68(11.63)	71.31(14.30)**	63.56(12.82)	66.31(13.01)*
Stride time(sec)	2.41(0.61)	1.91(0.20)*†	2.38(0.57)	2.15(0.40)
Step length of paralyticside(cm)	37.18(10.22)	44.37(7.61)**†	34.43(6.83)	38.12(7.93)*
Stride length(cm)	67.81(21.97)	75.87(16.40)**†	59.75(13.12)	64.12(12.58)*
SLS of paralytic side(%)	26.40(5.90)	30.64(5.92)**†	24.49(4.15)	26.65(4.70)

Values are presented as number or mean(standard deviation).

RGTR: robot-assisted gait training with RAS, RAS: rhythmic auditory stimulation, SLS: single limb support.

Between the group($^{\dagger}p<0.05$), within the group($^{*}p<0.05$, $^{**}p<0.01$).

Discussion

This study was conducted on hemiplegic stroke patients and performed RGTR training for 4 weeks to determine the effects on lower limb function, balance, and gait ability.

In this study, lower limb function exhibited a significant difference after training in both groups ($p < 0.05$), and not significantly was found when comparing differences between-groups. In a previous study, Kim et al. [11] reported that 3 weeks of robot-assisted gait training conducted on stroke patients effectively improved lower limb function. Lee et al. [10] reported that when bilateral RAS gait training was administered to stroke patients for 6 weeks, there was no difference between-groups in lower limb function. Similar to previous studies, this study both groups indicated significant enhancement in lower limb function after training, but no significant differences were identified when comparing differences between-groups. This suggests that both groups showed functional improvement in the lower extremities due to high-intensity repetitive gait training through robot-assisted gait training, but the RAS provided to the RGTR group did not appear to have a significant effect in enhancing lower limb function. Tian et al. [20] stated that a recruitment balance between agonist and antagonist muscles must be achieved to improve motor function, and that patients with hemiplegia have difficulty improving motor function through control of co-contraction.Additionally, Kibushi and Okada [21] reported that providing auditory feedback did not immediately improve co-contraction of muscle. Likewise, in this study, it was difficult to show improvement in lower limb function through RAS within a short period of 4 weeks, future studies should include longer training periods than this study to further explore the effects on lower limb function.

In the present study, SI of balance ability showed a significantly increased after training only in the RGTR group ($p < 0.05$). In addition, in BBS, both groups exhibited a significant increase after training ($p < 0.05$), and the between-group difference comparison exhibited a significant increase in the RGTR group relative to the control group ($p < 0.05$). According to a meta-analysis study by Loro et al. [22], balance rehabilitation through robot-assisted gait training in stroke patients significantly improved BBS scores. In addition, according to previous studies related to gait training throughRAS, gait training through RAS was effective in improving static and dynamic balance in stroke patients [23, 24]. This study showed similar results to previous studies. This suggesting that the RAS provided during the initial contact of the paretic side lower limb in RGTR results in continuous weight bearing on the paretic side lower limb compared to general robot-assisted gait training, improving stroke patients' asymmetric weight support and more effectively enhancing the ability to transfer weight to the paretic side, thereby positively impacting their balance ability.

Among the parameters related to gait ability, this study utilized information onvelocity, cadence, stride time, step length of paretic side, stride length, andsinglelimb supportof paretic side. The RGTR group exhibited significant change in all gait parameters after training ($p < 0.05$), andthe control group exhibited significant change in all gait parameters except stride time and single limb support of paretic side after training ($p < 0.05$). Additionally, in the between-group difference comparison, except for cadence, the RGTR group exhibited a significant difference relative to the control group ($p < 0.05$). High-intensity repetitive task training is a highly effective method to promote motor function recovery after stroke [25], and this can be provided more safely through robot-assisted gait training. Additionally, in order toeffectively apply robot-assisted gait training requires voluntary participation and active effort from the patient [26], and RAS training can be used to encourage such active movements. According to a study by Choi et al. [27], weight-bearing auditory feedback gait training for 6 weeks was found to be effective in restoringwalking speed andfunction. Yang et al. [28] conducted treadmill gait training with real-time auditory stimulation feedback for 4 weeks and found that the experimental group exhibited a significantly enhanced on walking speed, step length and stride length, single limb support of paretic side, and gait symmetry relative to the control group. Similar to the previous studies, the outcomes of this investigation also significant difference was confirmed in gait parameters except for the cadence. This that the RAS tempo provided to the RGTR group was set according to cadence that was 10% faster than the participants cadence measured before the experiment, It is thought that this regular tempo and high-speed auditory stimulation at such by repeatedly providing to the initial contact of the lower limb of paretic side, which had a positively impacting on improving gait ability by improving lower limb coordination along with changes in gait patterns.

Limitations of this study include the following. First, conducted with patients admitted to a single rehabilitation hospital, making it difficult to generalize the results. Second, there was no follow-up observation after 4 weeks of training, making it difficult to determine the long-term effects. Therefore, future research should address these limitations by conducting longer-term training and follow-up observations, lasting at least 8 weeks, to determine the effectiveness of RGTR on lower limb function, balance, and gait ability in hemiplegic strokepatients.

Conclusion

This study was conducted to explore the effects upon lower limb function, balance, and gait by applying RGTR to hemiplegic stroke patients.The results of the study revealed that RGTR is useful as a training program for enhancing balance and gait ability in stroke patients. Therefore, it is suggested to implement RGTR along with conservative exercise therapy as a training program to enhance balance and gait ability of hemiplegic stroke patients in the future.

Conflicts of interest

The author has no potential conflicts of interest in relation to the authorship and/or publication of this article.

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