Ambulation training for patients with acute stroke by Gait Trainer cyclic walking exercise and Functional Electrical Stimulation (FES): a pilot study

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Abstract

Gait trainer has been studied in stroke rehabilitation but the subject was limited in subjects with chronic stroke. This study evaluates the therapeutic effects of regular training (RT), gait trainer (GT) and cooperatively applying the functional electrical stimulation and gait trainer (GT-FES) for acute stroke survivors with hemiparesis. Twenty-six nonambulatory hemiparetic subjects, two to four weeks after stroke, were randomly assigned into one of the three gait intervention groups. Eleven subjects were trained with RT, eight subjects were trained to walk on GT that substituted for usual physiotherapy gait training, and seven subjects in GT-FES group received extra electrical stimulation applied on lower limb during gait trainer training. Mobility, ambulation ability, gait speed and lower extremity strength were assessed before and after the training. After a 4-week training, using intention-to-treat analysis, all the outcome measures showed significant improvement in all the 3 groups. For between-group comparison of the different scores between the 0 week and the 4 weeks, the GT and GT-FES groups scored significantly higher than the RT group for Functional Ambulation Category. Patients after stroke trained by the gait trainer with or without FES resulted in higher ambulation independency than conventional gait training.

1. INTRODUCTION

Gait in hemiplegic stroke people are generally greatly disturbed. More than one half of people after stroke who survive the acute phase were not able to walk while 50 percent walking impairments were still exists three months after the accident [1]. As a result, restoration of gait becomes a major goal in neurological rehabilitation after stroke.

In stroke rehabilitation, treadmill has been widely used in clinical settings [4]. The gait trainer and the treadmill both provide task-specific repetitive training of walking. The basic principle of neurological rehabilitation is that a skill will be improved if it is practiced repetitively. There is imaging and neurophysiological evidence that cortical reorganization can occur following stroke and recovery from stroke [5,6]. The ipsilateral hemisphere and the uncrossed corticospinal tract take over a role in movement control in the recovery from hemiplegia [7]. Forced repetitive active movement of a paretic limb appears to facilitate the recovery from hemiplegia by facilitating cortical re-organization and the utilization of ipsilateral pathways [8].

An electro-mechanical gait trainer designed by Hesse and co-workers [2] enabled wheelchair-bound subjects to practice a gait-like movement with minimal assistance. The advantages of the gait trainer help to relieve the strenuous effort of the therapists and able to provides a highly symmetrical, more independently gait practice for the non-ambulatory people. In fact, FES could be combined with the gait trainer in the training protocol to generate active movement from paralysed muscles. Although both FES and Gait Trainer have demonstrated positive therapeutic effects during post-stroke rehabilitation, the two have never been cooperatively applied to the study of strokes. As the therapeutic effect of Gait Trainer with the implementation of cycle-dependent FES is unknown, the objective of this study is to find out the effects of Gait Trainer coupled with cycle-dependent FES in acute stroke rehabilitation.

2. METHODS

Twenty-six subjects with hemiplegic acute stroke from the rehabilitation unit of the Tung Wah Hospital of Hong Kong fulfilled the inclusion criteria, and participated in the approved randomized, controlled, parallel-group study following written informed consent. The subjects were randomized into one of three groups: the routine treatment control (RT, n=11), gait trainer (GT, n=8), gait trainer coupled with functional electrical stimulation (GT-FES, n=7) groups. All subjects were evaluated before training, after two weeks, and at the end of the 4-week training period with outcome measures of Elderly Mobility Scale (EMS), Functional Ambulatory Category (FAC), gait speed and Motricity Index of lower limb. The experimental groups (GT and GT-FES) received gait training on the gait trainer while an additional functional electrical stimulation was applied to the paretic lower limb for the GT-FES group. For the GT-FES group, FES was used to stimulate the quadriceps muscles and common peroneal nerve and the stimulation was coordinated with the gait cycle of the gait trainer, in order to improve the gait quality in subjects with weak or paralyzed knee extensor and ankle dorsiflexor. The control group received conventional physiotherapeutic gait training based on the principles of the proprioceptive neuromuscular facilitation and Bobath concepts [3] which was performed by the subject's own therapist in the physiotherapy department.

Descriptive statistics were used to compare the baseline characteristics and the pretraining outcome measures of the three study groups. ANOVA was used to determine differences in the clinical outcome measures EMS, FAC, gait speed and MI (motricity index leg scores) difference scores across the three groups. The difference scores are calculated by subtracting the post-training score (4th week) by the pre-training scores (0 week). ANOVA, followed by Bonferonni post hoc comparisons, were used for comparing data reported in continuous, interval/ratio scales between the three groups (RT, GT and GT-FES). Friedman test and Kruskal-Wallis test were used for the nonparametric variable. Intention-to-treat analysis was used in data analysis. An alpha-level of $p<0.05$ was assumed.

3. RESULTS

82 stroke survivors were referred to the study. Five inclusion criteria were: diagnosis of ischemic brain damage or intracerebral hemorrhage less than six weeks; sufficient cognition to follow simple instructions as well as the content and purpose of the study; ability to stand supported or unsupported for one to two minutes (Functional Ambulation Category Scale (FAC) >=1); significant gait deficit (FAC scale<3); no allergy to electrical stimulation. 56 were rejected for not meeting at least one of the above inclusion criteria defined in this study. 26 subjects recruited were randomized into the RT group (n=11), GT group (n=8) and GT-FES group (n=7). 3 out of the 26 stroke survivors who admitted to the study did not complete the protocol (one was readmitted to an acute hospital, one had deteriorating medical condition and one was discharged prior to completion). No significant differences were found among all characteristics between the three groups at baseline as well as the pre-intervention outcome measures (mobility, functional ambulation, strength and gait speed). Intention-to-treat analysis showed that subjects in all the three groups improved in mobility, ambulation ability, walking speed and lower limb strength between the pretraining (week 0) and post-training (week 4) data. ANOVA followed by post hoc analysis revealed significant difference between the control group (RT) and the treatment groups (GT, GT-FES) for the FAC different score ($p=0.012$, $p=0.036$) only. There was no significant difference in all the outcome measures between the two treatment groups (GT and GT-FES).

	RT	***GT***	***GT-FES***
Strength	16.3	20.4	24.2
EMS	47.5	50.0	51.0
FAC	20.0	40.0	44.0
Gait Speed	30	36.7	54.4

Table 1: Improvement (%) on the pre- and post-evaluation between RT, GT and GT-FES groups

4. DISCUSSION AND CONCLUSIONS

The results of this randomized clinical trial indicated that gait trainer training and gait trainer with FES were superior to regular physiotherapy with regard to improvement of ambulation independency. However, the small sample size did not generate enough power to detect significant differences in other outcome measures between control group and the two treatment groups. The subjects with acute

stroke who received 4 weeks of gait training by body weight support gait trainer regained better ambulation ability than those who received similar gait training while bearing full weight on their lower extremities on level ground in the control group.

Walking speed was improved greatly for the two gait trainer groups. The subjects were trained at a faster comfortable speed on the gait trainer and the speed was monitored by the physiotherapist. The target training speed is based on the average walking velocity of functional walking of normal people, 1.1. to 1.5 m/s. The subjects in groups GT and GT-FES had reached a significantly higher gait ability level as compared with those in RT group shown from the FAC scores.

Some reports [9,10] stated that there is a short-lasting or long-lasting 'carry-over' effect after using the device for awhile just using FES intervention. Comparing with this study, the gait speed measured in two treatment groups, although not significant, showed greater improvement than the control group. In fact, GT-FES group has the highest scores in most of the outcome measures (mean differences ± SE): Motricity Index of lower limb (12.7 ± 6.1), gait speed (0.27 ± 0.12). This indicated that FES might improve the fitness and strength of the remaining motor units to which the subjects has voluntary control, by means of a training effect on them. FES potentially provides an artificial way of ensuring synchronized presynaptic and postsynaptic activity in the affected population of anterior horn cells, but it will only work if the electrical stimulation is combined with simultaneous voluntary effort, activating the residual pyramidal tract [8]. Therefore, when the electrical stimulus is applied at appropriate phase of the gait cycle in GT-FES group, the automatic toe-lift command during swing phase and knee extension command during stance phase are being generated in the brain, and sent via the depleted corticospinal tract. As a result, FES could be uniquely effective in promoting cortical reorganization. In this study, FES coupled with gait trainer may have better carry on effect to the people after stroke who only trained with gait trainer alone.

The effect of post-stroke ambulation training with gait trainer alone or coupled with FES was found to have significantly higher improvements in functional ambulation as compared with regular gait intervention. Long-term intervention and follow-up evaluation are necessary in future study.

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