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Research Article

Effect of Functional Electrical Stimulation with Lower limb Cycling on Lower Limb Motor Recovery, Balance and Ambulation among Individuals with Hemiparetic Middle Cerebral Artery Stroke

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Abstract

Functional Electrical Stimulation Training (FEST) during specific tasks can improve motor performance after stroke due to activity-dependent plasticity and brain remodeling. Functional electrical stimulation (FES) can be used to initiate lower limb muscle contractions and has been widely applied in lower limb rehabilitation. The purpose of this study was to find the effects of functional electrical stimulation and Cycling on the lower limb motor recovery, balance and walking on acute stroke in-patients. The study included 12 individuals diagnosed with acute stroke who fulfilled selection criteria and were randomly divided into experimental group that received functional electrical stimulation during various task training, and a control group that received only standard conventional exercises, with 6 subjects in each group. The study used a before–after study design. FES was incorporated into the task training for 45 minutes 5 days per week for 2 weeks. Pretest and Post test was assessed using outcome measures Fugl-Meyer Assessment Scale, Berg Balance Scale and Functional ambulation category for changes in lower limb motor recovery performance, functional balance and independence in walking.

Results show that in Fugl-Meyer Assessment Scale-Lower extremity, the experimental group scores ranged from 16.7 ± 3.72 to 26.05 ± 1.70 and the control group scores ranged from 16.3 ± 3.24 to 16.8 ± 3.76, which showed significant differences ($p < .05$) only in the FES Cycling group, and there was also significant difference between the groups ($p < .05$). The Berg Balance Scale scores and Functional ambulation category showed significant differences within experimental group alone ($p < .05$), but showed no significant difference between the groups ($p > .05$). The study concludes that the Functional electrical stimulation therapy with Cycling for 2 weeks along with standard exercises may be suggested as an effective therapy for improving lower extremity motor performance for acute stroke in-patients. Future studies should focus on using various control systems, sensors and for longer duration in order to harness the benefits of early intervention and neural plasticity.

Keywords: Functional Electrical Stimulation Cycling; FESC; FES; Lower limb Cycling; Stroke; Hemiplegia; Physiotherapy

Abbreviations

FES: Functional Electrical Stimulation; FESC: Functional Electrical Stimulation Cycling; MCA: Middle Cerebral Artery

Introduction

Worldwide, Cerebrovascular Accident or Stroke is the commonest cause of mortality after coronary artery disease. Stroke is one of the leading causes of disability in India (Pandian., *et al*. 2013). Looking into the epidemiology studies, there is an increase in incidence and prevalence in our country. The incidence rate is between 116 and 483/100,000 per year. The lifetime risk of stroke after 55 years of age is 1 in 5 for women and 1 in 6 for men [1].

The consequences of stroke encompass the deterioration of muscular strength, modifications in muscle tone, disruptions in postural stability, dysfunction of the upper limbs, challenges or the complete inability to ambulate, and a diminished quality of life. The incapacity or challenges associated with ambulation represent one of the most profound consequences of stroke, thus rendering the restoration of gait as a primary objective within rehabilitative practices. Gait-related activities encompass a range of tasks, including mobility during transitions from sitting to standing, sitting down, ascending stairs, turning, transferring (e.g., from wheelchair to bed or from bed to chair), ambulating at an increased pace, engaging in activities of daily living (ADL), instrumental activities of daily living (IADL), and walking over predetermined distances. Limitations in gait and gait-related activities are correlated with an elevated risk of falls [2,3].

A multitude of rehabilitation systems exist to support patients following a stroke, and we currently inhabit an era that emphasizes the integration of optimal practices derived from clinical trials, systematic reviews, and established guidelines. One such intervention is Neuromuscular Electrical Stimulation (NMES) or Functional Electrical Stimulation (FES). Functional Electrical Stimulation (FES) typically refers to the simultaneous or intermittent application of electrical stimulation in conjunction with a functional task, as initially articulated by Moe and Post. Evidence derived from diverse meta-analyses indicates that FES is efficacious in enhancing motor performance among individual's post-stroke. Its effectiveness is notably augmented when employed alongside other physiotherapeutic interventions. Guidelines recommend the consideration of electrical stimulation on an experimental basis within the initial two months following a stroke for individuals who exhibit muscle contraction but are unable to move their limbs in opposition to resistance [4-6].

Literature Review

A Randomized controlled trial on 40 individuals with hemiparesis by Bauer., *et al*. found that a 4-week (12 sessions) treatment of FES cycling helped to improve postural control, muscle strength and walking ability in subacute stroke patients. They suggested that active leg cycling when combined with FES the gait rehabilitation will be enhanced [7].

Elisabetta Peri., *et al*. in their single blinded Randomized controlled trial done on post-acute elderly stroke patients with FES-augmented cycling training combined with voluntary pedaling or standard physiotherapy. The intervention consisted of fifteen 30-minutes sessions carried out within 3 weeks. 15-sessions FES-augmented active cycling treatment and standard physiotherapy while the control group received an equal dose of standard physiotherapy only. Patients were evaluated before and after training, through functional scales, gait analysis and a voluntary pedaling test. Results were compared with an age-matched healthy group. Sixteen patients of mean age 71 years completed the training. His study showed that FES augmented active cycling training seems to be effective in improving cycling and walking ability in post-acute elderly stroke patients [8]. A case series design study on 12 chronic hemiparetic patients by Alon G., *et al*. found that an 8-week intensive FES cycling training protocol significantly improved the get up and go test times, gait velocity, and peak pedaling power. This study was without a control group and with a small sample size of 12, which limits the ability to generalize the outcomes. The patients were between 2 – 37 years post stroke and utilized an intensive training protocol that would not be appropriate for acute population [9]. Ambrosini E., *et al*. in their RCT on 30 patients with hemiparesis found that a 4-week treatment of FES cycling helped to improve motor recovery and walking ability in subacute stroke patients. This was a high-quality study with a 3-to-5-month follow-up showing a main effect in favor of the treatment. cycling also helped to improve muscle activation and symmetry of pedaling, suggesting improved involvement of the hemiparetic leg [10]. Ambrosini E., *et al*. in their RCT on 20 patients with subacute hemiplegia found that a 4-week intervention of FES cycling had significant improvements in motor strength and motor recovery than physical therapist assisted standard rehabilitation only. The entire intervention group recovered the ability to perform the sit to stand task at 3 different rising speeds while the standard rehab group did not [11]. Ambrosini E., *et al*. 2016, did a study on twelve healthy subjects with an age of >60 years and no previous history of neurological injury, and 16 post-acute stroke patients were recruited and studied for Cycling-Based Metrics and Gait Parameters. He found that the first synergy (knee extensors) and third synergy (knee flexors) produce the energy needed to propel the crank during limb extension and flexion, respectively. Significant correlations were found between cycling-based metrics and gait parameters, suggesting that neuro-mechanical quantities of pedaling can inform on walking dysfunctions. Their findings support the use of pedaling as a rehabilitation method and an assessment tool after stroke, mainly in the early phase, when patients can be unable to perform a safe and active gait training [12]. In a study by C.V. Shendkar, 14 adults experiencing foot drop <6 months poststroke were allocated to each of the the FES group or the control group. Each group received their respective therapy 5 days/week for 12 weeks. Gait, surface electromyography(sEMG) of the tibialis anterior muscle in the affected leg, and electroencephalogram (EEG) signals from the foot motor area were assessed at baseline and again after the 12-week intervention. Study showed that 3 months of FES intervention induced significant therapeutic effects in hemiplegic patients with foot drop. Comprehensive gait analysis revealed that FES improved quality of walking and foot clearance. These improvements are accompanied by changes in ankle muscle activation and cortical activity [13]. Shen., *et al*. in their Systematic review reported that cycling for lower limb with MOTOmed movement therapy combined with standard rehabilitation improves mobility and activities of daily living in stroke patients with hemiplegia [14].

Aim of the Study

This study aims to determine the effect of 2 weeks Functional Electrical Stimulation with Lower limb cycling on lower limb motor recovery, balance and gait among individuals with hemiparetic Middle Cerebral Artery Stroke.

Methodology

This Pilot Experimental study was conducted on acute in-patients diagnosed with stroke through magnetic resonance imaging (MRI) and computed tomography and referred for stroke rehabilitation. All patients were fully explained about the methodology and purpose of the study prior to participating in the study. And the patients voluntarily agreed to participate in the study The study used a before–after study design with control group. Those patients who fulfilled the following criteria were recruited for the study. Male and female aged 35 to 70 years diagnosed as MCA stroke by neuroimaging such as CT or MRI, Abbreviated Mental Test score more than 8, poor voluntary control on Brunnstrom stage of II for lower limb, able to perceive current, able to participate for 2 weeks, those who have no orthopedic disease which disturbs standing or walking, those who have no discomfort and contraindications for electrical stimulation. Those stroke patients who have cognitive impairment, perceptual dysfunction, any other conditions that affect their balance, recurrent stroke, existence of other neurological illness, participants with sensory issues, known psychiatric illness or depression, participant with cardio-respiratory illness, known degenerative, metabolic or traumatic musculoskeletal conditions which can interfere in FES training were excluded from the study. Twelve patients who met the selection criteria of the study were randomly allotted six in each group. Six patients were allotted to functional electrical stimulation therapy with cycling training which is the experimental group. Another six patients were in control group which received standard exercises only.

Procedure

This research was executed subsequent to the endorsement from the Human Ethics Committee of KMCH Hospital (EC/AP/1202/10/2024). For the selection of participants in this research, 60 patients referred for Physiotherapy underwent screening and were briefed regarding the objectives of the Functional Electrical Stimulation Therapy (FEST), alongside an explanation of the research methodology; ultimately, twelve patients who consented to participate in the training were enrolled. Prior to the commencement of FEST, demographic variables, including gender, age, inpatient registration number, and referral particulars, were meticulously documented. The experimental group participants received functional electrical stimulation during a variety of tasks along with lower limb cycling, whereas the control cohort engaged solely in conventional exercises for a duration of 45 minutes per day, five times per week, cumulating in a total of 20 sessions over a period of two weeks. All participants in both groups undertook standard muscle strengthening exercises, stretching regimens, and ambulation activities for 45 minutes. All patients were assessed using the Fugl Meyer performance test to evaluate the changes in recovery of lower limb motor performance, Berg balance scale (BBS) to evaluate the change in balance ability before and after the experiment, and a Functional ambulation category to evaluate the change in walking ability. All interventions were administered according to the individual functional level of each participant.

Functional electrical stimulation therapy

The functional electrical stimulation therapy apparatus employed in this investigation was the Mega XP FES Machine, which facilitated the stimulation of requisite musculature through a multichannel program during the transitions from sitting to standing, maintaining a standing position, and ambulation. Reference electrodes were strategically positioned on the proximal aspect of the musculature. The waveform utilized for the functional electrical stimulation was a square wave, with a frequency set at 35 Hz and a pulse width established at 300 microseconds. The intensity of the electrical stimulation was calibrated to elicit robust muscle contractions upon application of the electrical stimuli to the patient. The musculature subjected to stimulation encompassed the hamstrings, quadriceps, hip flexors, and tibialis anterior of the affected lower extremity.

Outcome measures

Fugl-Meyer assessment

The Fugl-Meyer Assessment (FMA) is an internationally recognized stroke-specific, performance-based impairment scale. Its design aims to evaluate motor function, balance, sensation, and joint functionality in patients recovering from a stroke. The FMA motor assessments for both upper and lower extremities are advocated as essential measures to be incorporated in all stroke recovery and rehabilitation studies. This scale was initially introduced by Axel Fugl-Meyer and his associates in 1975 as a standardized assessment tool for post-stroke recovery in their publication entitled "The post-stroke hemiplegic patient: A method for evaluation of physical performance." The scale encompasses five domains: motor function (in both upper and lower extremities), sensory function (evaluating light touch on two surfaces of the arm and leg, along with position sense for eight joints), balance (comprising seven tests, three in a seated position and four while standing), joint range of motion (spanning eight joints), and joint pain.

It features the upper extremity (UE) subscale (33 items; scoring range, 0–66) and the lower extremity (LE) subscale (17 items; scoring range, 0–34), culminating in a total motor FMA score of 100. The FMA sensory assessment is employed to evaluate limb sensation. Sensation is classified as absent, impaired, or normal for light touch (two items each for UE and LE; scoring range, 0–8) and proprioception (four items each for UE and LE; scoring range, 0–16), resulting in a total sensory FMA score of 24. The administration of the complete FMA typically requires approximately 30 to 35 minutes. The reliability of this assessment tool has been substantiated, with intra-rater reliability reported as r = .94 and inter-rater reliability as r = .99 [15,16].

Berg balance scale (BBS)

The Berg Balance Scale was formulated for the assessment of balance in the elderly population, serving as an evaluative instrument recognized for its validity concerning conditions such as stroke and traumatic brain injury. The Berg Balance Scale is segmented into three categories: sitting, standing, and postural changes, with a cumulative score of 56 points, assigning a minimum of 0 to a maximum of 4 points per item. This measurement tool demonstrates high validity and reliability, with intra-rater reliability reported as r = 0.99 and inter-rater reliability as r = 0.98 [17,18].

Functional ambulation category (FAC)

Functional Ambulation Category is a widely acknowledged clinical tool for gait assessment, first introduced by Holden., *et al*. in 1984. This functional evaluation of ambulation assesses the patient's status by determining the level of human assistance required. The FAC categorizes six distinct levels of walking ability based on the extent of physical support needed. The FAC functions as a rapid visual assessment of ambulation, is user-friendly, easily interpretable, and cost-effective, necessitating merely stairs and 15 meters of indoor flooring for its implementation. Furthermore, the FAC exhibits a robust correlation with performance-based gait assessments [19,20].

A FAC score of "0" (nonfunctional ambulator) signifies a patient who is unable to ambulate independently or necessitates the assistance of two therapists. A FAC score of "1" (ambulator, dependent on physical assistance [level II]) denotes a patient who requires continuous manual contact to support body weight, as well as to uphold balance or facilitate coordination. A FAC score of "2" (ambulator, dependent on physical assistance [level I]) indicates a patient who requires intermittent or continuous light touch to assist with balance or coordination. A FAC score of "3" (ambulator, dependent on supervision) represents a patient who can walk on a level surface without manual contact from another individual but requires standby supervision from one person for either safety or verbal prompting. A FAC score of "4" (ambulator, independent, level surface only) signifies a patient who can ambulate independently on level surfaces but requires supervision to navigate (e.g., stairs, inclines, or uneven surfaces). A FAC score of "5" (ambulator, independent) indicates a patient who can ambulate independently in all environments, including stairs [21].

Results

For the statistical evaluation of this research, the SPSS version 26.0 software application for Windows was utilized, with descriptive statistical analysis employed to characterize the general attributes of the participants. Data were evaluated for normal distribution utilizing the Shapiro-Wilk test, subsequently analyzed with the appropriate parametric tests. A paired t-test was conducted to ascertain the changes observed before and after the intervention within the group, while an independent t-test was utilized for inter-group comparisons. The threshold for statistical significance (α) was established at .05.

Data were analyzed for a total of 12 patients who participated in this study. The baseline characteristics are presented in the table 1. There was no significant difference between groups on the general characteristics of the subjects who participated in this study ($p > .05$), As a result of this experiment, there was significant difference in comparison between groups ($p < .05$) only in Fugl Meyer lower limb scores but not on other variables which is tabulated in Table 2). Also, the table 2. depicts significant difference on outcome measures before and after intervention in the experimental group alone ($p < .05$) but not in control group

Variables	Control group	Experimental group
Number of subjects(n)	6	6
Age of participants in years as Mean (SD)	56.83(10.02) *	49(9.03) *
Gender(Male/Female)	5/1	6/0
Side of stroke(Left/Right)	5/1	2/4
(Ischemic/Hemorrhagic type	4/2	6/0
Fugl Meyer lower extremity scores (0-34)	16.3(3.24) *	16.7(3.72) *
Berg Balance Scale (0-56)	20.66(3.59) *	20.49(3.38) *
Functional Ambulation Category (0-5)	1.33(0.46) *	1.16(0.36) *

Table 1: General characteristics of the participants (N = 12).

*Scores depicted as Mean (Standard deviation).

Outcome measures	Within Group-Scores	Control group	Experimental group	Calculated t Value
Fugl Meyer Assessment-Lower extremity	Pretest	16.3(3.24)	16.7(3.72)	5.46*
	Posttest	16.8(3.72)	26.5(1.70)	
	t Value	2.70	5.60*	
Berg Balance Scale (0-56)	Pretest	20.66(3.59)	20.49(3.38)	1.25
	Posttest	21.66(3.46)	22.49(3.99)	
	t Value	2.25	5.80*	
Functional Ambulation Category (0-5)	Pretest	1.33(0.46)	1.16(0.36)	1.19
	Posttest	1.5(0.5)	1.83(0.36)	
	t Value	1.01	3.09*	

Table 2: Within group and between group changes on motor performance, balance and ambulation (N = 12).

*P value < 0.05 significant within group (Paired t test) and between the group (Independent t test).

Discussion

The purpose of this study is to examine the effects of Functional Electrical simulation with cycling on the recovery of lower limb motor performance, balance, and walking on acute stroke in-patients. Experimental group participants received functional electrical stimulation and cycling for 2 weeks and the control group received only standard conventional exercises. Both the control group and the experimental group performed the appropriate tasks as part of early inpatient stroke exercise program for 45 minutes, 5 times a week, for a total of 20 times for 2 weeks.

Functional electrical stimulation (FES) constitutes a specialized category of neuromuscular electrical stimulation (NMES), wherein the stimulation facilitates functional and purposeful movements. This objective is realized by administering electrical stimulation to musculature that, upon contraction, engenders movement that may be utilized functionally. The absence of neural innervation resulting from neurological impairment inhibits muscular capacity to generate force. The application of electrical stimulation serves as a means to restore movement and the capability to execute activities of daily living. There exists level Ia and level II evidence indicating that FES has the potential to enhance gait, balance and range of motion. Furthermore, there is level Ib and limited level II evidence suggesting that peroneal nerve stimulation may augment gait and quality of life in post-stroke patients [22].

In the comparative analysis of the Functional Meyer – Lower Extremity (FM-LE) assessment to evaluate lower limb functional capabilities within this study, a statistically significant difference was observed in the experimental control group pre- and post-intervention only, additionally, a significant difference emerged in the comparative evaluation of changes between the experimental and control groups. These findings suggest that the application of functional electrical stimulation therapy may exert a favorable influence on lower limb recovery in individuals who have experienced a stroke. This phenomenon is posited to occur because FES assists in facilitating functional movement; it is hypothesized that the afferent-efferent stimulation induced by FES, which results in limb movements coupled with cutaneous and proprioceptive inputs during the acute phase, could be pivotal in “reminding” patients on how to execute movements correctly [23].

The limitations of this study are that first only the effect of FES on lower limb recovery and performance for 2 weeks was evaluated, and the long-term treatment effect could not be judged, and the follow-up test was not conducted. Second, this study focuses on stroke population starting only from early acute in-patients admitted for acute care and not done on all stages of stroke. 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 participants. Study can be performed further at multiple points in rehabilitation setting to understand impact of early FES on longitudinal recovery. Also, quantitative measures like EMG could be used to understand changes at motor unit level. More research is needed to determine the optimal timing and dosages of various patterns, channels and types of FES. The feasibility, cost effectiveness and patient perceptions of FES application in India is yet to be explored on a broader stroke population.

Conclusion

Functional Electrical Stimulation along with Lower limb Cycling is an effective therapy for improving lower extremity function of Stroke in-patients. Therefore, functional electrical stimulation may be recommended as part of the rehabilitation program for Individuals with hemiplegic Subacute Stroke.

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Conflict of Interest

There are no conflicts of interest.

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