A Study on the Effect of Functional Electrical Stimulation on Hand Function in Stroke Patients with Flexor Synergy in Upper Limb

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Abstract

Background and Purpose: To determine whether Functional Electrical Stimulation can improve motor function of hand in spastic hemiplegics and whether any improvements are maintained

Methods: 30 subjects of stroke with spastic hemiplegia with flexor synergy upper limb. 15 patients in each group, Group A (Functional Electrical Stimulation group) & Group B (Control group). Group-A received Functional Electrical Stimulation plus standard inpatient/outpatient stroke rehabilitation program. Group-B received only standard inpatient/outpatient stroke rehabilitation program. Assessment data were recorded before treatment, at 4, 8, 12 and 24 weeks. Outcome Measures were Action Research Arm Test Score, Range Of Motion of Active Wrist extension, Functional independence measure, Modified Ashworth Scale.

Results: Use of Functional Electrical Stimulation resulted in improvement of hand functions in patients. There was decrease in wrist flexors muscle tone and subsequent improvement in activities of daily livings observed. There was no significant improvement observed in Active Wrist extension.

Conclusion: Functional Electrical Stimulation is an important intervention in the treatment of stroke with spastic hemiplegia. It can help in the improvement of hand functions when prescribed along with exercises.

Key words: *Stroke, Hemiplegia, muscle spasticity, rehabilitation, Electric Stimulation, Exercise*

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Introduction

Mortality & morbidity due to stroke is very high across the world. Approximately 20 million peoples each year are expected to suffer from stroke and out of these 5 million will not survive[1]. 85% of stroke related deaths occur in developing countries[2].

Stroke mortality & morbidity in India has prevalence of 55.6 per 100,000 all ages (1), 0.63

million deaths[3], 1.44-1.64 million cases of new acute strokes every year[3, 4], DALYs lost due to stroke were 795.57 per 100,000 person-years[5] (730.43 in men and 552.86 in women), 12% of strokes occur in the population aged <40 years[6], 28-30 day case fatality[1, 7] ranges from 18-41%. Stroke is also a leading cause of functional impairments, with 20% of survivors requiring institutional care after 3 months & 15-30% being permanently disabled[8].

Brunnstrom[9] & Sawner[10] described the process of recovery following stroke induced Hemiplegia in 7 different stages. From the stage where minimal voluntary movement begins to appear a basic synergy pattern seen i.e. increased spasticity of some group of muscles hinder isolated joint movement. The flexor synergy of upper limb includes shoulder adduction, flexion, and internal rotation with elbow flexion, wrist pronation and flexion, and finger and thumb adduction, flexion into palm[9, 10, 11].

This pathological synergy is increased in the hemiparetic limb during efforts to use it for a specific task[12]. Often the individual is able to close the fingers into fist (part of the flexion synergy), but is unable to open the fingers. Abnormal synergies constitute significant impairment that needs to be addressed by rehabilitation[13].

The degree of post stroke motor recovery varies widely. It is directly related to the degree of initial severity and the interval from stroke to initiation of voluntary movement[11,14,15]. During this recovery period, motor recovery is believed to be enhanced by various techniques such as the neurodevelopmental techniques[16],sensorimotorintegration[17],proprioceptive neuromuscular facilitation[18], biofeedback[19] and functional utilization of evolving synergies[9]. These techniques seldom facilitate significant improvements in reaching, grasping & releasing functions and the patients are often released to home with a paralyzed arm.

There is a different approach which is based on functional electrical stimulation (FES) of muscles to augment hand function[20]. FES is a technology that uses short duration electrical pulses applied at skin and activates weak muscles to produce functional movements[21].

Objective of study was to determine whether FES can improve motor function of hand &any improvements are maintained after FES in spastic hemiplegic patients as per schedule.

Materials and Methods

We studied 30 hemiplegic stroke patients in a Prospective Interventional study comparing standard treatment with standard treatment plus FES, in each group 15 patients were taken for study. Patient was divided in 2 groups- Group A (FES group) & Group B (control group). All subjects in both groups received standard physical, occupational, & speech therapy interventions as per the inpatient/outpatient stroke rehabilitation program.

The study was approved by the National Institute for Locomotor Disabilities (NILD) Institutional ethics committee. Written informed consent was taken from the patient or a close relative. Patients attending Outpatient Department (OPD) and Inpatient Department (IPD) of NILD, Kolkata, India during the February 2015 to August 2016. Patients diagnosed to have stroke with hemiplegia with flexor synergy of upper limb. Subjects were randomly allocated through chit box method into two groups. It is a simple method of generating random sequence. For random allocation of 30 case into two groups equally, prepared 15 chits writing "A" (for group A) on 15 chits & "B" (for group B) on 15 chits. After folding the chits & putting in a box & well mixing, drew a chit, note the letter written on it, & then drew the second chit without replacing

the first, note it & proceed similarly until the last i.e. 30th chit is drawn.

Inclusion Criteria:

1. Unilateral stroke in a medically stable patient within 2 years of occurrence of stroke

2. Hemiparesis with presence of flexor synergy in involved upper limb

3. Age > 18 years

4. No limitation of passive joint range of motion in the involved limb

5. Have voluntary extension of wrist (of at least 10 degrees from the resting position) & fingers

6. Some active movements in affected shoulder & elbow

7. Adequate language function to respond to 2-step commands

Exclusion Criteria

1. Patients with flexor synergy due to cause other than stroke

2. No voluntary movement of the shoulder & elbow

3. Clinical evidence of shoulder subluxation (one finger with or more)

4. Presence of severe spasticity of wrist muscles (Modified Ashworth more than 2)

5. Mini-mental examination score <21

6. History of epilepsy/recent convulsions

7. Previous history of wrist problem (including previous hemiplegia or arthritis)

8. Presence of implanted electronic devices, respiratory insufficiency, hepatic or renal insufficiency, pregnancy, peripheral neuropathies

9. Received injection Botulinum toxin-A within last 3 months

10. Patients taking antispasticity medications

11. Active reflex sympathetic dystrophy or existing residual weakness due to lower motor neuron lesions of either extremity

12. Unable to express themselves in speech or to comprehend verbal or written information

13. Any co-morbid neurological disease (Lower motor neuron lesions of the impaired upper extremity, spinal cord injury, traumatic brain injury, multiple sclerosis, Parkinson's disease)

14. Intolerance of FES by patient

15. Dermatitis/burn in area of FES application

16. Unwilling to participate in study

Group-A: While using FES (MegaXP FES Machine, South Korea), patients were instructed to sit quietly for 30 minutes. Two electrodes of bipolar in configuration were used (active and indifferent) to generate a flow of current. Bipolar electrodes are both the same size meaning the current at each site will be equal. Bipolar systems enable greater targeting of muscles. Wrist & finger extensors, Extensor Carpi Radialis Longus (ECRL)/Extensor Carpi Radialis Brevis (ECRB), Extensor Carpi Ulnaris (ECU) & Extensor Digitorum Communis (EDC) were stimulated with a pair of non-adhesive electrodes. The skin surface electrodes with Meditech gel (Ultrasound Gel) were used for better conduction & comfort of the subjects. Diameter of Surface electrode (rubber pad) was 1.5 inch. Proximally over forearm below the elbow one electrode was placed, and the other one was placed distally on the forearm (positioned

for optimally balanced joint movement). Electrodes carefully placed to avoid either radial or ulna deviation of the wrist. If there is excessive ulnar deviation, the active electrode moved towards the ECRB on the radial side of the forearm. If radial deviation occurs, the electrode moved towards the ECU on the ulnar side of forearm.

The stimulus pulse was a symmetric biphasic rectangular waveform with amplitude ranging between 10-20 mA (depending on response), pulse width of 300 microseconds, frequency ranging between 25-35 Hz. Stimulation was given for 30 minutes' period/ day, 3 days/week for 8 weeks.

Total 24 sessions of FES were given. The current amplitude & frequency were adjusted to patient's comfort & response.

Group B (control group) - Received only standard conventional treatment/therapy. Therapy was continued consecutively for 24 sittings, thrice a week for 8 weeks.

Assessment data were recorded before treatment, at 4, 8, 12 (1st follow-up 4-week post FES) & 24 (2nd follow-up 16 weeks post FES) weeks.

Outcome Measures

1. Modified Ashworth Scale (MAS)

2. Action Research Arm Test (ARAT) score by ARAT Kit

3. Functional Independence Measure (FIM-self-care component) score- (Total Score 42)

4. Active Range of Motion of Wrist Extension (AROM)

Statistical Analysis

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 20.0.1 and GraphPad Prism version 5. Descriptive statistical analysis was performed to calculate the means with corresponding standard deviations (SD). Chi-square (χ^2) test was performed to find the associations. Paired t-test was used to compare the means. $p<0.05$ was taken to be statistically significant.

Findings

The patients who were included in this study underwent 5 assessments. Initially, 32 patients were included. Two patients dropped out of the study. One patient suffered from second attack of stroke and was discarded. Another patient was not regular for FES application, hence was also discarded. The final number of participants taken for data analysis was 30, 15 patients in each group. According to protocol of the study, patient population age > 18 year, who fulfilled inclusion criteria were eligible to participate in the study. The mean age of patients who were included after fulfilling the criteria of the study in FES group was 52.86 years and in control group was 53.13 years. However, no statistical significance difference was found between FES & control group. In our study, in FES group 73.3 % of patients were male & 26.7 % were female. Sex ratio was 2.7: 1. In control group, 60% male & 40 % female patients. Sex ratio was 1.5: 1. However, no statistical significance difference of this ratio was found between FES & control group. The association between the gender and age of study population was not found to be statistically significant. Mean duration of stroke was 7.3 months in FES group, 7.06 months in control group. However, no statistical significant difference was found between FES & control group. In FES group there were 33.3% left sided hemiplegics & 66.7% right sided hemiplegics. In control group there were 20% left sided hemiplegics & 80% right sided hemiplegics. However, no statistical significant

difference was found between FES & control group. (Table 1)

Table 1 Demographic characteristics

	FES Group	Control Group
Age in Years- mean(SD)	52.86 (12.36)	53.13 (9.73)
Sex : male –female ratio	11:4	9:6
Duration of stroke- months- mean(SD)	7.33 (5.12)	7.06 (4.54)
Side of Hemiplegia- Right: left	10:5	12:3
Height(cm) mean(SD)	165.2 (10.67)	162.13 (10.98)
Weight(Kg) mean(SD)	65.86 (9.5)	70.80 (4.6)

Discussion

At 4 weeks after giving FES mean ARAT score in FES group was 17.8 & statistically significant (p=0.0003) improvement. At 8 weeks mean ARAT score in FES group was 25.06 & statistically significant (p=0.0001) improvement. At 12 weeks & 24 weeks (follow-ups after completion of FES) improvement in ARAT score was maintained & was statistically significant. In ARAT score more improvement were observed at 8 weeks in grip & grasp sub-scores, in pinch or gross movement no significant improvement were seen. Achieved improvement in grip & grasp functions were maintained up-to 24 weeks.

The subjects mainly described functional improvement as better ability to grasp and release small objects and more functional use of the affected upper limb in the activities of daily living. Powell et al also found significant improvement in the grip and grasp scores of the ARAT as compare to the control group[22].

When comparing hand functions with FES at the 4 week and 8 weeks, the hand function is more improved at 8 weeks of FES application. All the patients in addition to FES were on conventional physical & occupational therapy at our institute & home based exercise programs and hence this improvement in hand function could be a combined effect of these factors. This implies that the continued use of FES along with therapy resulted in improved hand functions in these patients.

There was some improvement observed in Active Wrist extension in FES group at 8 weeks but no statistically significant difference was found between the two groups. Active wrist extension range was assessed by Powell et al found no significant improvement in active wrist extension[22]. We found no evidence in literature for improvement in active wrist extension ROM.

In present study wrist flexor spasticity of the affected limb was assessed. At 4 weeks no significant improvement was found in spasticity in two groups (p=0.13603). At 8 weeks statistically significant improvement was found in spasticity in FES group (p=0.0032). At 12 weeks (1st follow-up) statistically significant improvement was maintained. At 24 weeks (2nd follow-up) improvement in spasticity was

only maintained in 1 patient (6.7%) but in rest of patients (93.3%) spasticity returned to the base level (as before FES application). Study by Popovic et al found a decrease of tone in comparison to the control group[23]. King found a decrease in wrist flexor tone after FES in wrist extensors compared to stretching of wrist flexors[24].

At 4 weeks mean FIM score was 31.1 & statistically significant improvement was found in FIM score (p=0.0005). At 8 weeks mean FIM score was 32.5, was found to be statistically significant (p=0.0152). At 12 weeks (1st follow-up 4 week post FES) & 24 weeks (2nd follow-up 16 weeks post FES), statistically significant improvement in FIM score was maintained. Chae et al and Francisco et al observed significant motor improvement FES group compared to the control group on Fugl-Meyer test (FM) & FIM Score (self-care component)[25, 26]. Only 2 participants complained of pain and discomfort initially for few minutes during FES application. One patient complained of Skin redness after FES application. One patient suffered with one episode of vaso-vagal syncope & recovered and FES was continued. Otherwise no serious complications observed.

Table 2 ARAT score, FIM Score, Spasticity, and Wrist AROM

		Pre-FES		At 4 weeks(12 sessions of FES)		8 week(24 sessions of FES)		12 week(1st follow up post FES)		24 week(2nd follow up post FES)	
		FES	Control	FES	Control	FES	Control	FES	Control	FES	Control
ARAT Score, mean(SD)		9.86 (6.96)	8.46 (3.37)	17.8 (7.57)	8.86 (3.35)	25.06 (9.55)	12.4 (4.27)	25.66 (9.55)	12.8 (4.87)	26.0 (9.39)	12.8 (4.87)
AROM-degrees, mean(SD)		19.66 (9.15)	13.66 (4.41)	25.66 (8.42)	15.0 (4.62)	29.33 (10.49)	19.33 (7.03)	29.66 (10.43)	19.66 (6.6)	30 (10.17)	19.66 (6.6)
Spasticity (On MAS)	1	0	2	0	0	4	0	4	0	1	0
	1+	4	5	4	8	11	8	11	8	4	8
	2	11	8	11	7	0	7	0	7	10	7
FIM(Self-care component) Score, mean(SD)		28.4 (4.20)	25.4 (3.88)	31.13 (3.31)	26.26 (3.45)	32.46 (2.94)	28.66 (4.86)	33.33 (3.01)	28.66 (4.86)	33.33 (2.66)	28.66 (4.86)

Results are mean (SD) unless otherwise stated.

Limitations

There are few studies published on the use of FES for hand functions in stroke patients with flexor synergy of upper limb. In our study, isometric muscle strength of wrist muscles, motor co-ordination, motor dexterity scales were not included these may have some effect on the outcome. There is lack of uniformity in hand function pattern in stroke patients with flexor synergy of upper limb, which can result in variability of data. Studies at Larger level will be required to determine whether FES of upper limb muscles after stroke improved hand function and ADLs.

Conclusions

This study was conducted to find the effectiveness of FES on hand functions during Activity of Daily Livings in patients with CVA with spastic hemiplegics with flexor synergy in upper limb and the following findings were obtained by analyzing the parameters namely ARAT Score, ROM of Active Wrist extension, Spasticity (On MAS Scale), FIM Score (Self- care component). We were unable to find similar studies published in Indian setup.

FES is an important tool for improving the hand functions during ADLs in patients with CVA with spastic hemiplegics with flexor synergy in upper limb. FES in wrist extensors enhances motor functional recovery and decreases upper-extremity disability. This is evident from the results of our study which show that patients had improved hand functions & ADLs with FES application and improvement was maintained 16 weeks after FES application (at 1st& 2nd follow-ups). Effect of FES on spasticity was maintained for 4 weeks after discontinuation of FES. So effect of FES on spasticity was short term.

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Ethical Clearance- Taken from institutional ethical committee

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