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EFFECT OF FORCE PLATFORM BIOFEEDBACK TRAINING ON BALANCE AND LOWER LIMB FUNCTIONAL OUTCOME IN HEMIPLEGIC PATIENTS FOLLOWING STROKE

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ABSTRACT **Aim:** To determine the effect of force platform biofeedback training on balance and lower limb functional outcome in hemiplegic patients following stroke

Study design: Randomized controlled trial

Duration of the study: Three years starting from 1st May 2016

Setting: Department of Physical Medicine & Rehabilitation, Regional Institute of Medical Sciences, Imphal

Study population: 34 hemiplegic patients following first attack of stroke within 6 months of recovery were randomly assigned to study and control groups (n=17).

Intervention: Study group received biofeedback training using smart balance manager (SBMS) in addition to conventional rehabilitation therapy program while the control group received conventional therapy only. Variables (mobility, functional motor level and balance) were recorded before and at the end of treatment course using RMI, FIM and smart balance master.

Results: Patients in both the groups showed statistically significant improvement in lower limbs motor function and mobility, dynamic balance parameters, mean percentage weight bearing difference between paretic limb and non-paretic limbs and walking speed (cm/sec) after training. However inter group difference after the training were significant only in EPE (p=0.037) and percentage weight bearing difference (p=0.005). In static balance though there were no significant inter group difference, the study group showed more change scores than the control group.

Conclusion: force platform biofeedback training in hemiplegic post stroke patients provides beneficial effect on balance and symmetrical weight bearing but does not provide additional benefit in lower limb motor functions and walking speed.

KEYWORDS : Force platform biofeedback, Static and dynamic balance, Centre of gravity, Lower limb motor function, Stroke

INTRODUCTION

Stroke is a worldwide health problem with prevalence rate of about 1.54 per 1000 and death rate is 0.60 per 1000 in India.[1] The most common outcome is hemiplegia constituting 90% of stroke patients. Diminished balance in hemiplegic patients is one of the most common problems and is of major concern because balance is an essential part of all functional activities during sitting, standing and walking.[2] The principle within physical therapy is the reestablishment of balance function in patients following stroke.

This study was attempted to evaluate the effect of force platform biofeedback training on balance and lower limb functional outcome in hemiplegic patients following stroke.

MATERIALS AND METHODS

The study was carried out in the department of Physical Medicine and Rehabilitation Regional Institute of Medical Sciences Imphal for three year starting from 1st May 2016. A total of 34 hemiplegic patients following stroke within 6 months of the first attack confirmed by CT or MRI brain, admitted the department for rehabilitation management were recruited which were assigned into study and control groups by block of four randomization. All the patients have the ability to understand, follow three steps command and were able to stand without support for 2 minutes and walk independently or with support. Hemiplegic post stroke patients with history of previous neurological pathology affecting lower limbs and severe cognitive dysfunction were excluded. All the participants were informed about the nature of the study and those agreed to participate were asked to sign the informed consent form. The approval of the institutional Ethics Committee, Regional Institute of Medical Sciences, Imphal were taken before starting the study.

Outcome measures

1. Rivermead Mobility Index(RMI)

RMI is a measure of disability related to bodily mobility. It demonstrates the patient's ability to move his or her own body. Total scores range from 0 to 15 and a higher scores reflect better mobility. The RMI is valid and reliable[3] and its items cover a wide range of activities, from turning over in bed to running.

2. Functional independence measure (FIM)

The FIM is the functional outcomes measure developed by Uniform Data system for Medical Rehabilitation (UDSMR) and its validity and reliability in stroke is well establish.[4] It contain 18 items that measure independent performance in self-care, sphincter control, transfers, locomotion, communication and social cognition. The FIM scores range from 1 to 7: a FIM item scores of 7 is categorized as “complete independence”, while a score of 1 is “complete dependence”. Scores below 6 require another person for supervision or assistance. Possible total score ranges from 18 to 126, and lower score indicates more dependent in respect to functional activities.

3. Static and dynamic parameters of balance

The Smart Balance Manager System (Neuro Com, a division of Natus, 9570 SE Lawnfield Road, Clackamas, OR, 97015 USA, System Number 7277) consist of dynamic force plate which records body Centre of gravity (COG) in terms of static and dynamic balance. Static balance measures postural sway and dynamic balance measures patients' ability to reach 50% of limit of stability (LOS) in terms of movement velocity, target reaching and trajectory. Smart Balance Manager System (SBMS) also measures the differential weight bearing on the two lower limbs during comfortable standing. Test retest reliability of balance assessment using SBMS have been documented as valid indicators of functional balance measures.[5,6]

Intervention
Both the study and control groups were given standard conventional rehabilitation therapy program including range of motion and stretching exercises, motor control facilitation (Neurodevelopmental training- NDT) exercises and co-ordination activities. In addition to these, both the control and study group were given standing balance under the supervision of a therapist.

The patients in the study group were given additional force platform biofeedback training using body's Centre of gravity projected from the force platform of SBMS including long force plate system. The long force plate system has the versatility of training many lower limb activities like reaching, weight loading using body's Centre of gravity as visual feedback. The biofeedback training include practicing standing balance with proper body alignment, symmetrical weight bearing, and reaching peripheral target within the limit of stability (LOS). They were also trained to attempt reaching targets and loading activities mimicking daily activities involving lower limb functional activities like getting up, initiation of weight loading and reaching target while maintaining the body symmetry using the visual biofeedback.

These training were given 4 times in a week, each session lasting 30 minutes for 4 weeks. The subjects were examined and variables were recorded on baseline and at the end of treatment course.

STATISTICALANALYSIS
Data were entered in SPSS version 16. Descriptive analysis of baseline characteristics of both study and control group were done with chi square test (x^2) test for categorical variables and Mann-Whitney U test was used for continuous variables. Comparison between pre and post training data within each group were done with Wilcoxon Signed Ranked test. Change score of the outcome measures data were calculated by subtracting the pre-training score from the post training score. The inter group comparison of the change scores were done using Mann-Whitney U test. P-value <0.05 were taken as significant.

RESULTS AND OBSERVATIONS
A total of 34 stroke patients fulfilling the inclusion criteria were studied. The two patients (one each from study and control groups) did not complete the training program and their data were not included in the analysis. The study group consisted of 8 male and 8 female while the control group consisted of 9 male and 7 female. The base line characteristics of both the groups are presented in table 1. There was no statistically significant difference between the two groups in terms of age, sex, time since stroke, etiology and paretic side. The mean age for study group and control group were 59.44±9.91 and 60.568±.17 respectively. The mean time since stroke was 52.5±021.68 day and 53.312±5.24 days for study and control group respectively. Majority of the patients 50% (8) were of age between 60-70 years in both the groups. Cerebral infarction constituted 68.8% (11) in the study group and 81.2% (13) in control group. Majority of patients 62.5% (10) in the study group and 68.8% (11) in the control group were with left sided hemiplegia.

The baseline functional and balance parameters characteristics are presented in table 2. There was no statistically significant difference between the study and control groups. The RMI scores in the study and control groups were 9.31±1.96 and 8.56±2.31 respectively. In the study group mean FIM transfer and locomotion were 12.69±3.50 and 8.06±2.02 respectively while in the control group it were 12.503±.71 and 6.94±2.35 respectively. The mean COG alignment eye open and eye close lateral were -0.0056±1.2 and -0.0250±1.2 respectively and COG alignment eye open and eye close anteroposterior were -0.0031±8 and -0.0662±0.3 respectively in the study group while in the control group it were -0.3331±0.8, -0.273±0.8, -0.3155±0.3, and -0.0556±0.4 respectively. The mean composite scores of dynamic balance parameters RT,MVL,EPE and DCL in the study group were 1.52±0.42, 1.33±0.36,34.11±10.68, and 65.00±10.60 respectively while in control group it were 1.27±0.43, 1.27±0.50, 32.55±7.47, and 66.05±8.05 respectively. The mean percentage weight bearing difference between the paretic and non-paretic limbs was 13.37±8.31 in the study group and 12.25±7.55 in the control group.

Table 1: Balance characteristic of study and control groups

Variables		Study N=16	Control N=16	p-value
Age		59.44±9.91	60.568±.17	0.788
Sex	Male	8(50%)	9(56.2%)	1.000
	Female	8(50%)	7(43.8%)	
Duration(mean) in days		52.50±21.68	53.312±5.24	0.920
Etiology	Infarction	11(68.8%)	13(81.2%)	0.362
	Hemorrhage	5(31.2%)	3(18.8%)	
	Left	10(62.5%)	11(68.8%)	0.502
	Right	6(37.5%)	5(31.2%)	

Table 2: Comparison of baseline FIM, RMI, Static and Dynamic Balance Parameters, Weight bearing difference, walk across scores between study and control group

Variables		Study Group N=16 (Mean ± SD)	Control Group N=16 Mean ± SD	P-Value (0.05)
RMI		9.31±1.96	8.56±2.31	0.376
FIM	Transfer	12.69 ± 3.5	12.50±3.7	0.985
	Locomotion	8.06±2.0	6.94±2.3	0.117
Static balance	EO COG Align L	-0.0056±1.2	-0.3331±0.8	0.330
	EO COG Align AP	-0.0031±0.8	-0.3155±0.3	0.231
	EC COG Align L	-0.0250±1.2	-0.2731±0.8	0.719
	EC COG Align AP	-0.0662±0.3	-0.0556±0.4	0.304
Dynamic balance	RT (sec)	1.57±0.30	1.27±0.4	0.075
	MVL (deg/sec)	1.32±0.30	1.26±0.40	0.678
	EPE (%)	34.10±10.6	32.54±7.4	0.955
	DCL (%)	65.00±10.5	66.04±8.0	0.985
Weight bearing difference		13.37±8.3	12.25±7.5	0.818
Walk speed (cm/sec)		41.03±17.4	32.03±18.10	0.117

The table 3 represents the comparison of pre and post training RMI, IM motor scores, static and dynamic balance parameters, % weight bearing difference and walking speed in both the groups. Both the groups showed statistically significant improvement in mobility and lower limb motor function. The mean RMI score showed significant change in both the study and control groups between the pre training (9.31±1.9); 8.56±2.3) and the post training (13.12±0.8; 12.87±0.8) assessment. The pre and post training mean FIM transfer and locomotion scores are 12.68±3.4 vs 15.25±2.3 (p=0.001) and 8.06±2.0 vs 10.00±2.0 (p=0.000) respectively in the study group and 12.50±3.7 vs 15.62±2.6 (p=0.000) and 6.93±2.3 vs 9.62±2.1 (p=0.001) respectively in the control group. Statistically significant improvement in dynamic balance parameters measured in terms of RT (1.57±0.30; 1.27±0.4 vs 1.98±0.3; 1.67±0.3), MVL (1.32±0.3; 1.26±0.4 vs 1.80±0.2; 1.61±0.3), EPE (34.10±10.0; 32.54±7.4 vs 50.10±8.0; 39.92±7.2) and DCL (65.00±10.5; 66.04±8.0 vs 80.37±9.0; 74.14±10.3) were found in both the study and control groups. However the mean postural sway recorded in terms of COG alignment displacement in lateral and anteroposterior direction in static standing with eye open and eye closed did not show any significant change between the pre training and post training assessment in both the groups.

The study showed statistically significant improvement in weight bearing on the paretic limb (13.37±8.3 vs 6.87±3.7; p=0.000) and walking sped (41.03±17.4 vs 45.37±21.9; p=0.000) after the training. There were no significant changes after the training in the control group.

Table 3: comparison of pre and post training RMI, FIM motor scores, static and dynamic balance parameters data, % weight bearing difference between paretic and normal limb

Outcome measures		Study group		P Value	Control group		P value
		Pre training	Post training		Pre training	Post training	
RMI		9.31 ±1.9	13.12 ±0.8	0.000	8.56 ±2.3	12.87 ±0.8	0.000
FIM	Transfer	12.68 ±3.4	15.25 ±2.3	0.001	12.50 ±3.7	15.62 ±2.6	0.000
	Locomotion	8.06 ±2.0	10.00 ±2.0	0.000	6.93 ±2.3	9.62 ±2.1	0.001
Static Balance	EO COG L	-0.005 ±1.2	-0.038 ±0.4	0.151	-0.333 ±0.8	-0.140 ±1.0	0.604

	EO COG AP	-0.003 ±0.8	-0.046 ±0.6	0.362	-0.317 ±0.2	-0.272 ±0.4	0.532
	EC COG L	-0.025 ±1.2	-0.216 ±0.5	0.534	-0.273 ±0.8	-0.081 ±1.1	0.417
	EC COG AP	-0.066 ±0.3	0.125 ±0.7	0.881	0.055 ±0.4	0.0550 ±0.4	0.074
Dynamic balance	RT (sec)	1.57 ±0.30	1.98 ±0.3	0.001	1.27 ±0.4	1.67 ±0.3	0.026
	MVL (deg/sec)	1.32 ±0.3	1.80 ±0.2	0.000	1.26 ±0.4	1.61 ±0.3	0.006
	EPE (%)	34.10± 10.6	50.10± 8.0	0.000	32.54± 7.4	39.92± 7.2	0.000
	DCL (%)	65.00 ±10.5	80.37 ±9.0	0.000	66.04 ±8.0	74.14 ±10.3	0.013
% wt bearing diff		13.37 ±8.3	6.87 ±3.7	0.000	12.25 ±7.5	10.87 ±6.3	0.147
Walk Speed		41.03 ±17.4	45.37 ±21.9	0.029	32.34 ±18.1	37.9 ±16.9	0.133

Table 4: Comparison of the changes sores of RIM, FIM static and Dynamic balance Parameters %weight bearing difference and walking speed after training in the study and control group.

Outcome variables		Study Group N=16	Control Group N=16	P value
RMI		3.81 ±1.6	4.31±1.5	0.286
FIM	Transfer	2.56 ± 1.5	3.12± 2.2	0.797
	Locomotion	1.93 ±0.5	2.68± 1.7	0.258
Static Balance	EO COG L	0.54 ± 0.6	0.07± 0.6	0.146
	EO COG AP	0.25 ±0.2	0.26± 0.1	0.472
	EC COG L	0.40 ±1.0	0.03± 0.5	0.352
	EC COG AP	0.35 ± 0.4	4.44± 11.5	0.508
Dynamic Balance	RT	0.41± 0.3	0.39± 0.5	0.806
	MVL	0.48 ± 0.2	0.35± 0.3	0.405
	EPE	16.00 ± 12.0	7.37± 5.1	0.037
	DCL	15.37 ±9.7	8.09± 10.0	0.061
% wt bearing difference		-6.50 ± 5.1	-1.37± 3.7	0.005
Walk speed		4.33 ±5.6	5.57± 14.0	0.835

Table 4 represents the comparison of the changes scores of RMI, FIM motor, static and dynamic balance parameters, and % weight bearing difference and walking speed after training in the study and control groups. Though both the study and control groups showed statistically significant improvement in mobility and lower limb motor function after the training, there were no statistically significant inter groups difference in RMI (p=0.286) and FIM self-care (0.208), FIM transfer (0.797), FIM locomotion (0.258) and total FIM (0.159) change the scores after training.

Though there was significant improvement in dynamic balance in both the study group and control groups, only EPE (p=0.037) showed statistically significant difference in changes score after training between the study and control groups. Static balance change score and mean walk speed change score did not showed any statistically significant difference between the study and control groups. There was statistically significant difference in the percentage weight bearing difference score between the study and control groups.

DISCUSSION

Balance is the prerequisite for all functional activities and is the key focus area for the therapeutic intervention after stroke. It is diminished in hemiplegic post stroke patients in terms of increase postural sway, asymmetrical weight bearing and decrease limits of stability (LOS). The present study was done to see the effect of force platform biofeedback training on balance and lower limb functional outcome in hemiplegic patients following stroke. It revealed that force platform biofeedback training in addition to conventional rehabilitation program does not provide additional benefits in terms of mobility, lower limb functional recovery and recovery and static balance in our group of hemiplegic patients following stroke.

External visual and auditory biofeedback in relearning of postural control in rehabilitation programs is believed to be effective therapy for improving balance function. However scientific researchers give different opinion regarding biofeedback force platform training effects on balance and lower limb motor recovery.

Yang DJ et al[7] provide in support of incorporating biofeedback postural training for the improvement of weight distribution and functional ability of stroke patients.

The presents study showed that mobility and lower limb motor function improve significantly in both the groups for hemiplegic patients following stroke after training when compared to pre-training score; however there were no significant inter group differences. Some authors reported similar findings. Eser F[8] and colleagues who investigated the effects of balance training, using force platform biofeedback in 41 hemiparesis patients following stroke by randomized controlled, assessor blinded trial observed that motor recovery mobility and activity level improved significantly in both groups (p<0.05). Inter- group difference of mean change score was not significant for the RMI (2.9 vs 2.2) and FIM score (10.7 vs 11.5). Similar findings were also reported by Geiger RA et al[9] in their randomized control trial study of 13 hemiplegic patients who ranged in age from 30 to 77 years and were 15 to 538 days post stroke.

The present study results supported the systematic review findings of Van Peppen RPS et al.[10] They reviewed randomized controlled trials and controlled clinical trials, comparing visual feedback therapy with conventional balance treatments up to April 2005. The meta analysis (8 out of 78 studies, presenting 214 subjects, demonstrated non-significant summary effects size in favor of visual feedback therapy for weight distribution and postural sway as well as balance and gait speed. The review concluded that the additional value of visual feedback therapy in bilateral standing compared with conventional therapy showed no statistical significant effects on symmetry of weight distribution between paretic and non-paretic leg, postural sway in bilateral standing, gait and gait related activities. However in contrary to their review the present study showed significant improvement (-6.50±5.1 vs -1.37±0.37; p=0.005) in weight bearing symmetry between the paretic and non-paretic limb in the study group who received force platform biofeedback training in addition to conventional therapy program when compared to the control group. The probable reason for the difference was that the post training assessment of balance parameters and functional motor outcomes were done just after the completion of 4 weeks training in the present study whereas most of the study in their review, post training assessment was done after 1-6 months, by that time carry over effect might have been lost. Similar observation with the present study was reported by Goljar N et al.[11]

The study contradicted the finding of Singh NR et al[12] and Chen IC et al[13] study. Singh NR et al observed that the hemiplegic patients gain more functional independence in terms of FIM transfer and locomotion with improved postural control following centre of pressure biofeedback. Chen IC et al also showed that visual feedback balance training with the smart balance Master was beneficial for patients after hemiplegic stroke. They also showed significant improvement in static balance parameters in all the patients after training but no significant inter groups difference. The present study did not revealed any significant improvement in static balance parameters in both the groups after the training. This finding in the present study might be due to wide range difference in the baseline COG alignment displacement between the study group and control groups (the study group had less COG displacement) and small size study population.

Walker C et al[14] conducted a study to compare the relative effectiveness of visual feedback training of Centre of gravity (COG) position with conventional physical therapy following physical therapy following acute stroke in 46 patients within 80 days of stroke. They found that all the hemiplegic patients demonstrated marked improvement in outcome measures of static and activity based balance function when pre and post training scores were compared but no inter group difference were detected. However in the present study inter group significant difference was seen in dynamic (EPE) and percentage weight bearing difference change score but not in walking speed.

Barclay-Goddard RE et al[15] in their review of 7 randomized control trials comparing force platform with visual feedback and or auditory feedback to other balance treatments found that force platform feedback improve stance symmetry but not postural sway in standing. Similar observations were also seen in the present study and Krekora et al.[16]

Tsaklis PV et al[17] in their pilot study to evaluate the effect of weight shift training on functional balance, weight distribution and postural control measures during standing and forward reach tasks in subjects with chronic stroke patients revealed that weight-shift training program improved balance control but not weight distribution in chronic stroke patients. However the present study showed improvement in dynamic balance (EPE) and in weight distribution.

Winstein CJ et al[18] conducted a study on 21 matched hemiparetic adults. Experimental group received balance training in a specially design device, which provided dynamic visual information about relative weight distribution over bilateral limbs. The control group received conventional hospital assigned physical therapy. Their study results revealed that standing balance including Centre of pressure position, weight distribution and stability were in those with augmented feedback training, but locomotor control performance was not differential affected by the two therapy modes. Similar observations were also made in the present study that dynamic balance (EPE) and percentage weight distribution between the paretic and non-paretic limbs significantly improved after training in hemiplegic post stroke patients who received additional force platform biofeedback training but there was no significant improvement in functional lower limb recovery in terms of mobility, transfer, locomotion and walking speed. Such findings could be due to lack of task specific lower limb motor training in the present study. It has been reported in some literatures that the balance retraining was context or was task specific. In a study Khallaf ME et al[19] showed a positive long lasting effect of the task specific exercises, gait training, and visual biofeedback on equinovarus gait pattern among individuals with stroke. Another study by Dean CM et al[20] observed a strong evidence of the efficacy of task related motor training in improving the ability to balance during seated reaching activities after stroke. Weight shifting tasks performed in our study might be helpful in improving percentage weight bearing on the paretic limb during quit standing and dynamic balance stability but this did not translate into functional improvement in gait.

There were limitations in the study such as non-blinding, where neither patients nor the observer were blinded, small sample size, short duration of treatment and lack of long term follow up.

CONCLUSION

Force platform biofeedback training in hemiplegic post stroke patients has additional beneficial effect on dynamic balance in terms of EPE and weight bearing symmetry in standing. But it does not provide additional benefits in static balance and lower limb motor functions including walking speed. Force platform biofeedback may be a therapeutic option for improving dynamic balance in patients suffering from hemiplegia when combined with conventional rehabilitation programs.

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