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Original Article

Physical Medicine and Rehabilitation Section

Effect of Body Weight Support Treadmill Training on Gait Recovery, Lower Limb Function and Dynamic Balance in Patients with Chronic Stroke: A Randomised Controlled Trial

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ABSTRACT

Introduction: Stroke is an omnipresent health problem that causes impairments in multiple domains and often leads to serious long-lasting consequences like pathological gait patterns. Gait rehabilitation is an important criterion for improvement in functionality. Body Weight Supported Treadmill Training (BWSTT) is being used as a method of gait rehabilitation, but efficiency of this method beyond traditional training is lacking evidence.

Aim: To evaluate the effect of body weight supported treadmill training on gait recovery, lower limb function and dynamic balance in chronic stroke patients.

Materials and Methods: A randomised controlled trial conducted in the Department of Neurorehabilitation of a specialty hospital, on 30 ambulatory chronic stroke patients having post stroke duration of six months or more. Study subjects were randomised into two groups. Group A received BWSTT with conventional rehabilitation for four weeks. Group B received only conventional rehabilitation for four weeks. Duration of conventional rehabilitation was 40 minutes in each group. Along with that group A received 20 minutes BWSTT and group B received 20 minutes of conventional gait training. Therapy was given three days a week. Assessment tools were Timed Up and Go test (TUG), Cadence, 10 metre Walk Test and Berg Balance Scale (BBS). The paired t-test was used for intragroup analysis and the unpaired t-test was used for intergroup analysis.

Results: Total of 30 patients were registered in the study with mean age (years) 52.07±3.6736 and 52.40±3.906 for group A and group B, respectively. There was significant improvement in all outcome measures, e.g., BBS, TUG, 10 metre walk test and Cadence, in both the groups, pre and post intervention, but group A showed statistically significant improvement in parameters like dynamic balance, walking speed, and postural control and walking function ($p<0.05$).

Conclusion: The BWSTT offers improvement in gait, in terms of walking speed, dynamic balance, posture control, that is significantly more than that of conventional gait training, as found in this study. The BWSTT might be included as a part of stroke rehabilitation program. Further multicentre studies with larger samples can throw more light on the intensity, dosage and methods of using BWSTT.

Keywords: Cerebrovascular accident, Gait rehabilitation, Hemiplegia

INTRODUCTION

Stroke is a serious global health problem that can cause multiple disabilities. Depending on the region of the brain affected and its severity, a stroke survivor incurs motor weakness, sensory deficits, cognitive impairments, visual perceptual disorders, and swallowing difficulties in various degrees [1,2]. Gait is an important parameter for prognosticating the functional independence, mobility, and disability post stroke [3,4]. Despite the substantial recovery of independent ambulation, persistent asymmetric and abnormal gait patterns like decrease in paretic side stance phase and non paretic side swing phase, cadence, velocity, inequality in step and stride length are observed in a large percentage of patients [5-7].

These disturbances in gait are caused by muscle weakness, impaired tone (spasticity, flaccidity, dystonia), and poor neuromuscular control. Gait control involves the planning and execution from multiple cortical areas, such as the secondary and premotor cortex [8-10]. A well-designed gait training focusing on repetitive motor training has been shown to facilitate brain neuroplasticity in stroke patients, thus resulting in early and enhanced motor recovery [11-16].

Bodyweight Supported Treadmill (BWST) is a well-established neurorehabilitation tool, used for gait restoration [17-19], that works on the principle of repetitive task-oriented approach. The higher intensity, repetitiveness, and task-oriented practice, offered in the same period with decreased physical assistance from a therapist, gives an added advantage over conventional therapy [11]. Several randomised controlled trials have demonstrated that BWSTT induces greater corticomotor excitability over regular physiotherapy leading to improved balance and gait speed in chronic stroke [11,17,19,20]. Franceschini M et al., have reported that BWSTT can increase walking endurance in the subacute stage after stroke, but not balance or gait speed [21]. Again, another study on stroke have reported no efficacy of BWSTT over conventional gait training [22].

Mehrholz J et al., in their review of the Cochrane database have found gait speed and endurance to be improved in those who underwent BWSTT although not statistically significant [23]. In a randomised controlled trial done by Tilson JK et al., an improvement in gait speed of 0.16 m/s was recommended to be the Minimal Clinically Important Difference (MCID) which can reduce the level of assistance in patients with subacute stroke [24].

Very few studies have adequately addressed the effect of unloading limbs through BWSTT on motor retraining [25,26]. As gait speed responds to short term rehabilitation the purpose of this study was to evaluate the effectiveness of a BWSTT intervention as a short term intensive program for chronic stroke survivors.

MATERIALS AND METHODS

This randomised control trial was conducted in the Department of Neurorehabilitation, of a Tertiary Care Hospital, in Kolkata, West

Bengal, India from January 2019 to July 2019. The research project was approved by the Ethics Committee of the Institute (Letter No. I-NK/EthicsComm/57/2016). The study has been carried out in accordance with The code of ethics of the World Medical Association (Declaration of Helsinki) for experimentation with human subjects.

The study team locked the data for six months after recruiting the first patient. The trial registration was done in the clinical trial registry of clinicaltrials.gov (Clinical Trail Registration Number: NCT04491162).

Inclusion criteria: Participants of both genders between 18 and 69 years of age were included. Patients with first episode of supratentorial arterial stroke (ischaemic or haemorrhagic) with hemiparesis after at least six months from onset of stroke from the Neurology and Neurorehabilitation Inpatient and Outpatient Department were also included in the study.

Exclusion criteria: All patients with neurological or musculoskeletal disorders affecting balance or motor performance of the trunk and lower extremities other than stroke were excluded. Patients with recurrent or bilateral Cardiovascular Accident (CVA) or severe cardiopulmonary disease (myocardial infarction within the past six months, angina or ischaemia at rest or during exercise, unstable hypertension (>150/90 mmHg), arrhythmia, congestive heart failure) were excluded. Those who had used nerve stimulation or botulinum toxin injection in the last three months were also excluded.

Study Procedure

All the patients were able to follow the advice and able to walk at least 10 metres distance independently, with or without walking aids at a walking speed <0.75 m/s at their Self-Selected Velocity (SSV). They must be scored at least 3 in the Functional Ambulation Category (FAC) Scale [28] and 21 out of 23 on the Trunk Impairment Scale (TIS) [29]. None of the patients received any other advanced physiotherapeutic intervention for gait training.

Thirty stroke patients were recruited, satisfying the selection criteria during this study period. It was an observational registry by the investigators. The sample size was calculated not based on a power calculation but through discussion of clinical matters based on defining an appropriate number of stroke patients that would represent the heterogeneity of lower limb impairment and facilitate a report on the feasibility, management, and efficacy of the intervention under the stated research conditions. This sample size was considered feasible for the researcher to deliver with the available time scale and resources, including staff assisted access to patient records, identification of suitable patients and invitation to participate in stroke, and completion of data collection within a limited period.

Subjects fulfilling the selection criteria were divided into two groups, group A (experimental group) and group B (control group), through computer generated block randomisation code which was generated by a member who was not a part of the study group. After taking informed consent, the individual allocation of the patient was revealed to the therapist.

The patients were tested with the outcome measure scales on day 0 and after the completion of intervention at four weeks, by an assessor who was not involved with the therapy. The assessor was blinded about the allocation of the subject into different groups. Data analyst was also blinded.

Both the groups, group A (experimental group) and group B (control group) received 40 minutes of conventional rehabilitation supervised by the same team of rehabilitation professionals. It included a holistic combination of medical management, occupational therapy, speech, language and swallow therapy, orthotic management, and conventional physiotherapy based on motor control strategies.

Additionally, group A received 20 minutes of BWSTT and group B received 20 minutes of overground gait training. Blood pressure and pulse were monitored electronically during every training phase and training was discontinued if blood pressure raised to or above 200 mmHg systolic or >110 mmHg diastolic or pulse rate was more than 160/min. Therapy was given three days a week, for four weeks. The outcome measures were assessed on day 0 and at the end of treatment after four weeks by an assessor who was blinded about the treatment allocation. The patients were instructed not to discuss their treatment allocation to the assessor.

The BWSTT system comprises of suspension unit which has an overhead horizontal bar and a harness (helps in offloading the body weight of the subject over the treadmill) attached with a pelvic band and two thigh straps. The harness is attached to the suspension system with a force transducer that signals the amount of offloading. The amount of weight to be offloaded is adjusted with the help of a remote. The maximum weight offloaded is 80% of body weight and the minimum is 20%. The treadmill provides a horizontal movement. There is a horizontal bar for the patient to hold on.

In group A, every BWSTT session of 20 minutes was supervised by the same physical therapist. Patients were advised to wear comfortable footwear, preferably sports shoes. A demonstration of the machine and the process was given on day 0 before the start of the study. The SSV of the patient was recorded on overground walking (G1). On day 1, the patient was advised to walk with BWSTT at G1. On day 2, the speed was increased to V1 (V1= G1+10% of G1). Thereafter, every week patient was motivated by the therapists to increase the speed gradually by 10% of the preceding week's speed. A 40% of body weight was offloaded throughout the study. The slope of the treadmill was not increased. The patient was instructed to hold on to the horizontal bar to avoid falls.

Scales Used

Berg Balance Scale (BBS) [30] is a 14-item scale ranging from 0–4 to a total score of 56 used to assess static and dynamic balance during functional activities. The risk of falls is high in subjects with a score of less than 40.

Timed Up and Go test (TUG) [31] measures the time that a person takes to rise from a chair, walk three metres, turn around, and return to the chair. Participants used their regular footwear and their usual mobility aid.

A 10 metre walk test [32] measures walking speed in metres per second over a short distance. It is used to determine functional mobility, gait, and vestibular function. Cadence is the number of steps per minute.

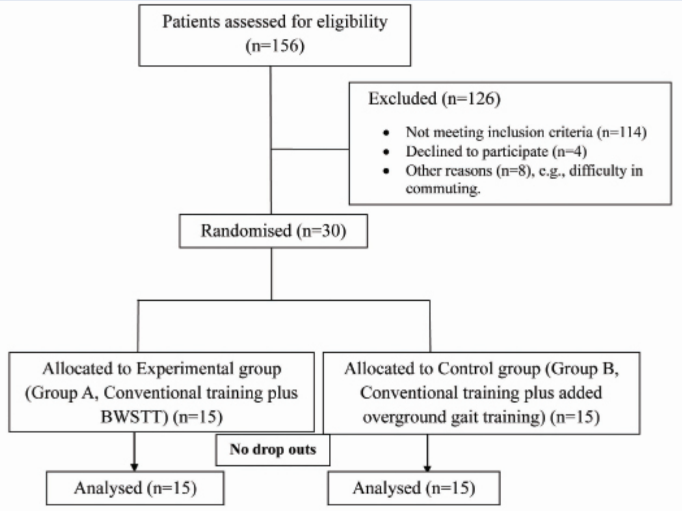
STATISTICAL ANALYSIS

The statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 23.0 according to the requirements of the study to compare the pre and post intervention values of the outcome measures that are BBS, TUG, 10 metre walk test, and cadence. The primary analysis consisted of the use of descriptive statistics for calculating the mean and Standard Deviation (SD). The paired t-test was used for intragroup analysis to compare the difference between pre intervention and post intervention of each of group A (experimental group) and group B (control group) and the unpaired t-test was used for intergroup analysis to compare the difference in pre intervention and post intervention between group A and group B. Within group, normality was tested using Shapiro-Wilk test and data was found to be normally distributed. The level of significance was set at $p<0.05$.

RESULTS

A total of 156 patients of chronic stroke were screened according to inclusion and exclusion criteria. Among them 126 were excluded and 30 were registered for the study. Fifteen participants were selected for each group {experimental group/group A (n=15) and conventional group/ group B (n=15)} for the study of four weeks duration. Excellent compliance was observed among the study subjects. All of them completed all therapy sessions, there were no drop outs. Two subjects, who missed one session each, were rescheduled in the same week [Table/Fig-1].

All demographic and pretraining outcome variables did not differ significantly among the two groups, so both the groups were comparable at the baseline [Table/Fig-2,3].



[Table/Fig-1]: CONSORT Flow chart

Demographic variables	Group A (Experimental group)	Group B (Control group)	p-value
Age (years) (mean±SD)	52.07±3.6736	52.40±3.906	0.814*
Gender (male/female)	8/7 (53%/47%)	9/6 (60%/40%)	1.000*
Hemiparetic side (right/left)	7/8 (47%/53%)	5/10 (33%/67%)	0.7104**
Type of stroke (ischemic/ haemorrhagic)	6/9 (40%/60%)	5/10 (33%/67%)	1.000**

[Table/Fig-2]: Demographic data of Group A (n=15) and Group B (n=15).
*Unpaired t-test/**Chi-square test; p<0.05 is considered to be significant

experimental group were responsive and well-tolerated to this new method of gait rehabilitation. Although most patients initially needed some manual support by the physiotherapist, the need for this was reduced eventually with practice trial on day 0. Patients who tended to deviate laterally were trained to centralisation of position with mirror feedback in the gym accompanied by verbal cue by the therapists. Similar to Srivastava A et al., there were no side effects like muscle soreness, tiredness, falls and cardiovascular problems which have been reported by other authors [22,33-36].

A hemiparetic person has a markedly slower walking speed than a non paretic person and the increased energy cost of walking fosters less willingness to move [6,7,16]. Walking speed is an objective and easy to monitor parameter in gait retraining. Improved speed translates into better negotiation of real world over ground obstacles and provides street safety, independence, and confidence in a daily functional context. In group A, the walking speed (mean 0.5607 m/sec) as well as cadence (mean 87.13 steps) were increased significantly post BWSTT. In performance sports, it is known that speed training gives greater results when maximal, as opposed to submaximal, speeds are used [37,38]. So, the progressive increase in speed in BWSTT might have been beneficial. The kinematic gains of BWSTT over conventional gait training in stroke has previously been reported by other researchers [19,39]. In treadmill training, the increased hip extension of the stance leg helps to initiate the swing phase and provides the temporal cue for stepping. Additionally, the offloading in BWSTT facilitates step initiation. This increased hip joint motion from stance to swing phase generates ground reaction force anteriorly and helps in the forward propulsion of the body. The temporospatial parameters like stride and step length have been seen to be increased in BWSTT translating to increased cadence and walking endurance [39,40]. This probably explains the improvements observed in present study as well.

Parameters	Group A (Experimental group)			Group B (Control group)			Intergroup p-values**	
	Pre intervention	Post intervention	p-value*	Pre intervention	Post intervention	p-value*	Pre intervention	Post intervention
TUG (Sec)	32.57±8.66	18.30±3.49	<0.001	31.57±7.89	26.25±6.82	<0.001	0.742	<0.001
Cadence (Steps/min)	66.73±21.94	87.13±17.89	<0.001	64.33±21.61	69.73±21.25	<0.001	0.765	<0.001
10MWT (m/sec)	0.30±0.11	0.56±0.23	<0.001	0.3067±0.10	0.3853±0.13	<0.001	0.893	0.016
BBS	43.73±3.53	49.53±2.85	<0.001	43.27±3.31	46.53±3.31	<0.001	0.712	<0.001

[Table/Fig-3]: Intra & Intergroup comparison of pre intervention and post intervention values (n=15 in each group).
TUG: Timed up and go; 10MWT: 10 meter walk test; BBS: Berg balance scale
*Paired t-test for intergroup comparison; **Unpaired t-test for intergroup comparison; p<0.05 is considered to be significant, Intra and Intergroup

The [Table/Fig-3] also shows a statistically significant improvement in all study parameters after the intervention, in group A compared to group B, indicative of a greater clinical benefit for the BWSTT group.

The TUG was used to measure the dynamic balance. Thus, if dynamic balance improves, the value of TUG will decrease. The average TUG score was noted before intervention and post intervention (four weeks). The difference was found to be statistically significant in both the groups. Thus, there was improvement after intervention. Similarly, BBS which is also a measure of dynamic balance in this study showed significant improvement in both the groups pre & post intervention, using paired t-test. Pre and post intervention values of Cadence were also highly significant in group A, as well as group B. The 10 metre walk test showed statistically significant difference in both the groups, before and after intervention. From the [Table/Fig-3], it may be conferred that conventional therapy, as well as BWSTT can bring out statistically significant changes in the gait and balance parameters of the chronic stroke patients.

DISCUSSION

This monocentric, randomised controlled trial was designed to evaluate the effect of short term intensive BWSTT on gait speed and balance in patients of chronic stroke. Overall patients in the

In the present study, TUG and BBS were used as outcome measures to assess functional balance. Before the intervention, the TUG score was >30 seconds in both groups and after the intervention, it became 26.25 seconds in group B and 18.3093 seconds in group A. Although both these values are more than 14 seconds which indicate a high risk of fall, the significant improvement in the experimental group shows an optimistic trend. Similarly, the BBS score of group A (49.533) vs group B (46.53) post intervention is statistically significant. In BWSTT, the constraints of the harness provide vertical alignment and stability of the trunk and the perturbation based training in a safe environment decreases the fear of fall throughout gait training [41]. Dragunas AC and Gordon KE, have suggested that BWS may reduce the requirement for the nervous system to actively stabilise laterally. The supplemental sensory information and increased joint position sense cause better foot placement [42]. Also, the mediolateral trunk regularity decreases the step width variability and increases the step width [40]. These principles might have been crucial in the improvement in functional balance and decreasing gait asymmetry noted in present experimental group.

Modern concepts of motor learning favor early intervention with task specific repetitive training [19] to improve motor recovery and functional outcome in stroke. Visintin M et al., and Mao YR et al., have concluded BWSTT can be started in the very early phase as well as subacute phase of stroke rehabilitation when the requirement for weight support as well as the potential for neuroplasticity is the maximum and is beneficial over conventional gait training [19,39]. Enthusiastic results of present study contribute to the growing evidence that neuroplasticity and neural recovery can occur in the chronic phase of stroke as well with task specific, repetitive, high intensity training. Additionally greater participant autonomy in a dedicated environment enhances locomotor performance and independence. However, Cochrane review found moderate evidence for walking speed and walking endurance and low evidence for improving the ability to walk independently and insufficient evidence for long term sustainability with BWSTT [23]. Recent research has coupled BWSTT with virtual reality and found to decrease the anterior pelvic tilt thereby beneficial in correcting abnormal circumduction gait pattern on the sagittal plane in hemiplegics [43] while the randomised controlled trial of BWSTT with robotics did not reveal substantial benefit [44].

All these are provided by conventional over the ground gait training. To date, there is no consensus regarding the intensity, duration and frequency of BWSTT [21].

Limitation(s)

The sample size was less, and there was a lack of follow-up. The heterogeneity of the age of participants could have led to some bias. Effect of any previous rehabilitation was not analysed. Double blinded design would have been a better option. The BWSTT also has certain limitations. It lacks the provision of natural stimuli to challenge different components of gait like anticipatory posture control, reactive control, and functional variations in gait such as turning, rising from a chair, starting or stopping [45].

CONCLUSION(S)

Use of BWSTT can lead to an unequivocal improvement in gait parameters, balance and lower extremity function, as shown in the study. The study has demonstrated that it is feasible to conduct gait training program for chronic stroke patients with significant improvements in gait parameters with or without BWSTT, but addition of BWSTT has given superior results than conventional therapy alone. Improvement in gait provides the chronic stroke survivor with opportunities to get integrated in the community and reduces the caregiver burden. Further trails with larger sample size and long follow-up can substantiate our evidence and help in the development of long term stroke rehabilitation program to reduce disability and optimise functional outcome.

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