



EFFECTIVENESS OF RESTORATIVE APPROACH VERSUS CONVENTIONAL APPROACH ON BALANCE AND GAIT IN SUBJECTS WITH TRAUMATIC BRAIN INJURY

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Abstract: The purpose of the study was to find the effectiveness of restorative approach versus conventional approach on balance and gait in subjects with Traumatic Brain Injury. A total of 86 subjects were screened with clinical diagnosis of Traumatic Brain Injury and randomised into two groups. As per the Glasgow Coma Scale(GCS), only individuals with mild to moderate level injury were involved in the study. The subjects in group-A (N=35) received restorative approach while the subjects in group-B (N=35) received conventional approach. Intervention was given to participants for 5 days a week for 4 weeks. The Berg Balance Scale for balance(BBS) and Functional Gait Assessment for gait(FGA) were used to assess the intervention's effectiveness. Independent t-test was used to compare the mean significant difference between continuous variables. Paired t-test was used to assess the statistical significance difference between pre and post test scores. This thesis has provided a transparent overview of an RCT evaluating the efficacy of a goal oriented and conventional approach aiming to ameliorate balance and gait performance in subjects with TBI. The present study concluded that both restorative approach and conventional approach are equally effective in improving balance and gait performance. However restorative approach was more effective when compared to conventional approach in terms of improving balance and reducing gait abnormalities. The preliminary evidence displayed how an individualized treatment approach resulted in high levels of goal attainments among participants in intervention group.

INTRODUCTION

Traumatic Brain injury is defined as “An alteration in brain function or other evidence of brain pathology, caused by external force”.¹ Traumatic Brain injury is often referred to as “silent epidemic” and represents the greatest contributor to death and disability globally among all trauma related injuries. TBI is a global health issue and is affecting around 69 million people every year.² In India, it is estimated that nearly 1.5 to 2 million people are injured. 2 million people die nearly and nearly 1 million people require rehabilitation every year.³ Of these, RTIs are the leading cause (60%) followed by falls (20%-25%) and violence (10%). Alcohol involvement is known to be present among (15 -20%) of TBIs at the time of injury.⁴

Symptoms vary greatly depending on the severity of the head injury, they may include vomiting, lethargy, headache, confusion, paralysis, loss of consciousness, dilated pupils, vision changes (blurred vision or double vision, unable to tolerate bright light, loss of eye movement, blindness), Cerebrospinal fluid (CSF) appear from the ears or nose, dizziness and balance concerns, sensitive problems, breathing problems, cognitive difficulties, inappropriate emotional responses, speech difficulties.⁵

Despite advances in our knowledge of the complex pathophysiology of TBI, the underlying mechanisms are yet to be fully elucidated. According to the unique **physical mechanisms** of insult, TBI can be divided into four categories.^{5,6}

1. Those from **External forces** hitting the head or the head hitting hard enough to cause brain movement. Injuries include those with skull fracture and those without skull fracture (closed head injuries). Direct blows to the head can cause coup injuries(at the site of impact) and countercoup injuries(distant from the site of impact).
2. Severe **acceleration and deceleration** of the head, which can cause TBI without the head hitting an object. For instance, shaken baby syndrome.⁷
3. **Penetrating TBI** results when foreign body penetrates the skull and traverses through the dura into brain parenchyma. Similar to closed head injuries laceration of brain tissue primarily causes focal damages, intracranial haemorrhage, cerebral oedema and ischemia.^{8,9}
4. In **blast injuries**, the brain is compromised by rapid pressure shock waves generated from explosion, which transmits a tremendous amount of energy from the skull into the enclosed brain parenchyma.^{10,11}

While initial brain insult involves acute and irreversible primary damage to the parenchyma, the ensuing secondary brain injuries often progress slowly over months to years hence providing window for therapeutic interventions.^{7,9}

PRIMARY INJURY

The two main mechanisms that causes primary injury are contact

- I. An object striking the head.
- II. The brain striking the inside of the skull.⁹

Primary injury due to **contact** may result in injury to the scalp, fracture to the skull or surface contusions. **Contusions** are distinct areas of swollen brain tissue. They are typically found on the poles of the frontal lobes, inferior aspects of the frontal lobes, the cortex above and below the operculum of the sylvian fissures and the lateral and inferior aspects of the temporal lobes.

Primary injury due to **acceleration deceleration** results from unrestricted moment of the head and leads to shear, tensile and compressive strains. These forces can cause intracranial **hematoma**, **diffuse vascular injury**, and the injury to cranial nerves and the pituitary stalk. Intracranial Hematoma is the most common cause of death and clinical deterioration after TBI.^{9,10}

TBI hematomas can be categorised as follows:

Epidural Hematoma

These are usually caused by fracture of the temporal bone and rupture of the middle meningeal artery with epidural hematomas, clotted blood collects between the bone and the dura. Because the source of bleeding is arterial, this type of hematoma can grow quickly and create pressure against the brain tissue.

Subdural Hematoma

Such hematomas are usually caused by rupture of the bridging veins in the subdural space. They can grow large enough to act as mass lesions, and they are associated with high morbidity and mortality rates.^{7,8}

Subarachnoid Hematoma

Result from damage to blood vessels in the posterior fossa.

Diffuse Axonal Injury(DAI)

One of the most common and important pathological feature of TBI. It constitutes mostly microscopic damage and it is often not visible on imaging studies. The main mechanical course that cause DAI is rotational acceleration of the brain, resulting in unrestricted head movement. Rotational acceleration produce shearing and tensile forces and maximum can be pulled apart at the microscopic level. Microscopic evaluation of the brain tissue often shows numerous swollen and disconnected axons. Rapid stretching of axons is thought to damage the axonal cytoskeleton and therefore, disrupt normal neuro function.⁸

SECONDARY INJURY

Secondary injury may occur hours or even days after inciting traumatic event, injury may result from impairment or local declines in cerebral blood flow (CBF) after a TBI. Decrease in cerebral blood flow are the result of local oedema, haemorrhage, or increased intracranial pressure(ICP). As a result of in adequate perfusion, Cellular ion pumps may fail, causing a cascade involving intracellular calcium and sodium. Resultant calcium and sodium overload may contribute to cellular destruction.⁹ Excessive release of excitatory amino acids, such as glutamate and aspartate, exacerbates failure of the ion pumps. As the cascade continuous, cells die, causing free radical formation, proteolysis and lipid peroxidation. These factors can ultimately cause neuronal death.¹²

TBI complications include posttraumatic seizures (frequently occur after moderate or severe TBI), hydrocephalus, deep vein thrombosis (incidence as high as 54%), gastrointestinal and genitourinary complications (among the most common sequelae in patients with TBI), **gait abnormalities**, agitation (common after TBI), chronic traumatic encephalopathy (CTE). TBI is also associated with a wide spectrum of neuromuscular, cognitive and behavioural impairments that can lead to limitations in activity, restrictions in social participation and diminished quality of life.^{13,14} **Balance deficits** and postural instability are very prevalent in people with traumatic brain injury (Walker and pickett 2007). It affects 39-62% of individuals following traumatic brain injury(Marsh et.al.2016).¹⁵

Physical therapy offers a unique non-pharmacological, non-invasive that incorporate different regimes to decrease disability.¹⁶ Winston and kay posit that effective rehabilitation must engage and empower the individual, and to do so requires the active ingredients to be 1)challenging 2)progressively increasing in level of difficulty, and 3)intrinsically motivating and engaging.

Restorative approach focuses more on the affected part to reinstitute functional independence and it contains strategies that avoid non-use and promote adaptive neuroplasticity especially with evidence supporting optimal techniques, timing and dosage of rehabilitation. Skill acquisition is better accomplished with context relevant, goal directed activities.^{16,17}

Conventional approach is a traditional treatment program which incorporates various ways of analysing moment, identifying key impairments and employing motor learning principles within the context of patients' goals, environmental constraints and task requirements (Schenkans Deutsch and Gill-Body, 2006) and it seeks to become popular as a promising strategy to improve quality of life in subjects with traumatic brain injury.^{18,19}

Considering all these potential benefits, the aim of the treatment is to compare the effectiveness of Restorative approach and Conventional approach on balance ability and Gait in subjects with traumatic brain injury.

NEED OF THE STUDY.

Traumatic brain injury is the most severe injury type among trauma related accidents and more than 70% of trauma related deaths are estimated to occur in low and middle-income countries.

Gait abnormalities and balance deficits are common and devastating consequences warranting special consideration that a physical therapist is likely to encounter.

Restorative approach and conventional approach are significant in the treatment of motor and functional impairments after traumatic brain injury.

Conventional Rehabilitation theories are based on the assumption that a hierarchical sequence of recovery steps must be followed to restore normal function and challenging patients too quickly or encouraging compensatory strategies too early is seen as a waster effort, if not potentially counterproductive.

Restorative therapy aims to improve outcome by salvaging threatened brain by promoting plasticity within surviving neural tissue. To date, fewer studies are available on restorative physical therapy in the management of the traumatic brain injury.

The differing perspectives continue to co-exist in the literature and there is dearth of empirical evidence to guide a clinician's decision making as to when to provide patient centred interventions.

Purpose of this study is to ascertain the effects of restorative approach in traumatic brain injury and to provide a sample of the evidence supporting effectiveness may be presented.

RESEARCH METHODOLOGY

Study Design : Randomised Controlled Trail

Ethical Clearance and Informed Consent : The study protocol was approved by Ethical Committee of GSL Medical College and General Hospital (Annexure-I), the investigator explain the purpose of the study and given the subject information sheet. The participants were requested to provide their consent for participation in the study (Annexure-II). All the participants signed the informed consent and the rights of the included participants have been secured.

Study Population : Subjects with Traumatic Brain Injury clinically diagnosed by Neurologist.

Study Setting : This study was conducted at Department of Physiotherapy, GSL Medical College and General hospital, Rajamahendravaram, Andhra Pradesh, India.

Study Duration : This study was conducted during the period of one year between October 2021-September 2022.

Intervention Duration : 4 weeks.

Treatment Duration : 30 min/session, 5 days/week for 4 weeks.

Type Of Sampling : Systematic Random Sampling.

Sample Size : A total of 86 subjects were screened, in that 73 subjects were recruited in the study. Recruited participants were explained the purpose and the relevance of the study. The participants were included in the study after obtaining informed consent. All eligible participants were allocated into two groups by systematic random sampling method.

Group A - Restorative group (36)

Group B - Conventional group (37)

Materials Used:

- Stopwatch
- Stairs
- Obstacles of 9 inches
- Step or stool
- Chair with armrests
- Chair without armrests
- Ruler
- Objects to pick up from floor
- Examination couch
- Data collection form

INTERVENTIONS

A total of 70 subjects with traumatic brain injury were involved in this randomised control trial with outcome assessments as berg balance scale and functional gait assessment. All the participants were screened and recruited according to the inclusion and exclusion criteria, by employing systematic sampling patients were randomly assigned into two groups, Group A(experimental group) and Group B(control group) each containing 35 subjects. Pre-intervention baseline measures were taken before the first intervention day and then the groups underwent a 30 min treatment protocol of 5 days/week for four weeks duration. 3 subjects were dropped out from the study due to secondary complications. The post baseline outcome measures were recorded immediately after the end of treatment.

PROCEDURE

GROUP-A RESTORATIVE APPROACH:

The Restorative approach aims at reinforcing, strengthening or restoring the impaired skills. The training program consists of tasks with a hierarchical progression of increasing attention demands, graduating from simple to complex distracters.^{16,17}

An appropriate strategy for overcoming limited functional activities is the task oriented approach, which focuses on goals and the surrounding environment to maintain balance during functional activities, it is important to effectively integrate visual, somatosensory and vestibular information.

This kind of exercise focuses on executing functional task in accordance with the following principles :¹⁹

- Repetition practice.
- Gradual increase in the complexity of the task.
- Training is based on the individual's goals and personal needs.
- This way of motor learning plays an emphasis on skill education through active learning and is related to neuroplasticity changes in the cerebral cortex, brainstem, cerebellum and spinal cord.

Each exercise session will be structured in three blocks of 20 minutes, each focusing on gait performance and balance control. The level of difficulty to the patient will be increased day by day by assigning tasks above the patient's capacity and by decreasing the time to carry out a task. A rest interval of 5 minutes can be given, whenever it is required by the patient in one exercise period.

EXERCISE PROTOCOL

I. TASK ORIENTED BALANCE TRAINING

Intervention	Instructions
Task oriented balance training (progressively challenging practice of selective voluntary movements with large amounts of repetitions).	<ol style="list-style-type: none"> 1. Sitting on a chair and reaching for objects in all directions at a distance of more than arm's length. 2. Stepping forward, backward, sideways on the exercise step. 3. Performing flexion and extension of affected knee with affected leg on exercise step and the unaffected leg off the step. 4. Stepping over obstacles with different heights. 5. Standing up from a chair, walking four steps forward, touching a stool and then returning to the chair. 6. Sitting on a Swiss ball while doing a range of motions and balance exercises in the trunk and upper extremities. 7. Double leg standing for 10 seconds. 8. Tandem standing 10 seconds. 9. Standing up from a chair without using the arms. 10. Tandem, walking forward and backward.

II. DUAL TASK PERFORMANCE (progressively more cognitive or motor tasks can be added while ambulating).

Intervention	Instructions
PRIMARY TASK	<ol style="list-style-type: none"> 1. Walking forward and backward. 2. Walking on S shaped route. 3. Walking and obstacle crossing. 4. Tandem walking.
SECONDARY TASK	<ol style="list-style-type: none"> 1. Simple arithmetic calculations. 2. Repeating words 3. Counting a digit number forward or backward. 4. Walking while answering simple questions (from the recording or general knowledge issues) 5. Reciting a short sentence backward. 6. Encourage to remember and speak out information from a certain category or phenomenon.
a) Cognitive	
b) Motor	<ol style="list-style-type: none"> 1. Catch and throw. 2. Holding one ball. 3. Bouncing basketball.

III. GAIT TRAINING

Intervention	Instructions
Gait Training (parallel bars/supportive aids can be encourage if needed).	<ol style="list-style-type: none"> 1. Walking forward and backward. 2. Walking and obstacle crossing. 3. Tandem walking.

GROUP-B CONVENTIONAL APPROACH:

Exercise program consists of a series of therapeutic exercises to retrain motor and functional abilities. At the initial stage session will not exceed 30-40 min and it will be gradually increased to 55-60 min.18

EXERCISE PROTOCOL

Instructions	Therapeutic goals
<p>Exercises while sitting on a chair with feet flat on the floor (1–2 min each; max 10 min) Mark time, raising the heel. Progress to alternatively lifting the entire foot and placing it on the floor on a footprint. Add alternating arm movements. Make two cross marks on the floor and alternatively glide the foot over; forward/backward, left/right. Rise from the chair, and then sit down in coordinated manner. Perform reciprocal flexion-extension of the arms and legs, imitating walking while sitting. Using a stick or ball for the upper extremities, coordinate movements of the upper and lower extremities. Follow a moving object with the eyes and head for eye-hand coordination. Sit on the Swiss ball slowly rocking from side to side, back and forth Bend trunk to the left and right to touch the ground. Sit on the Swiss ball while holding stick at the level of chest, rotate slowly clockwise and counter-clockwise. Sit-stand from the Swiss ball.</p>	<p>To improve: multi-segmental coordination. sitting balance. body awareness. range of lower extremity movement. movement precision. eye-head and eye-hand coordination. to reduce intention tremor.</p>
<p>Exercises while standing erect with feet apart (2 min each; max 20 min) Stand still on the floor, with or without support. Stand still on the rocker board, with or without support. Transfer weight onto the front, back and sides, narrowing the support surface. Stand on one leg: with and/or without arm movements. Turn to the right, raise the right toe and rotate the right foot outward, pivot on the heel, raise the left heel and pivot the left leg inward on the toes, and complete the turn.</p> <p>Exercises while walking (2 min each; max 15 min) Walk sideways, beginning with half steps to the right, bring the left foot over and repeat on the other side. Walk forward between two parallel lines 14- inches apart. Walk forward, placing each foot on a footprint traced on the floor 2-inches from a centre line. Walk backward. Walk on the toes or heels.</p>	<p>To improve: static and dynamic balance during double and single stance, walking agility gait pattern arm-leg coordination during walking gait initiation termination and walking with different bases of support</p>

Statistical Analysis

All Statistical analysis was done by using SPSS software version 21.0 and Microsoft excel-2007. Descriptive data was presented in the form of mean +/- standard deviation and mean difference percentages were calculated and presented.

Within the groups: Paired student “t” test was performed to assess the statistical difference within the groups for balance and gait from pre-test and post-test values.

Between the groups: Independent student “t” test was performed to assess the statistically significant difference in mean value between the groups for Berg Balance Scale for balance and Functional Gait Assessment for gait.

For all statistical analysis, $p \leq 0.05$ will be considered as statistically significant.

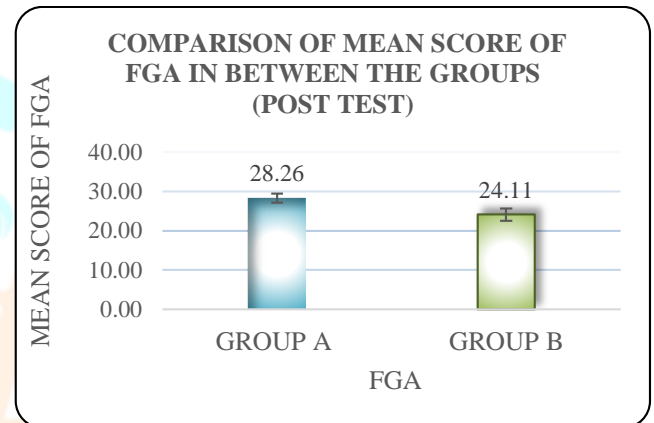
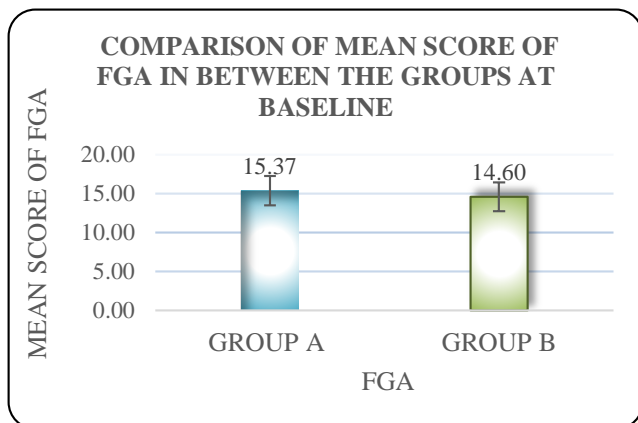
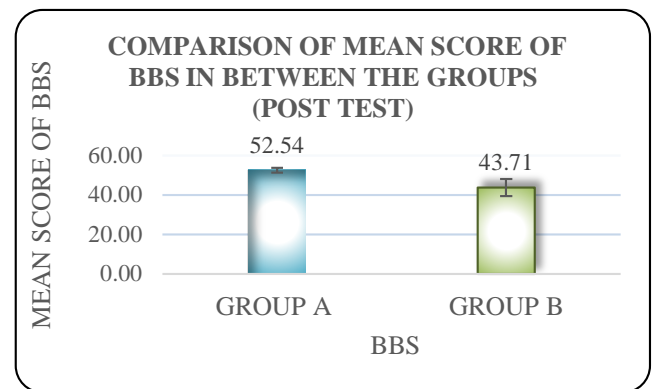
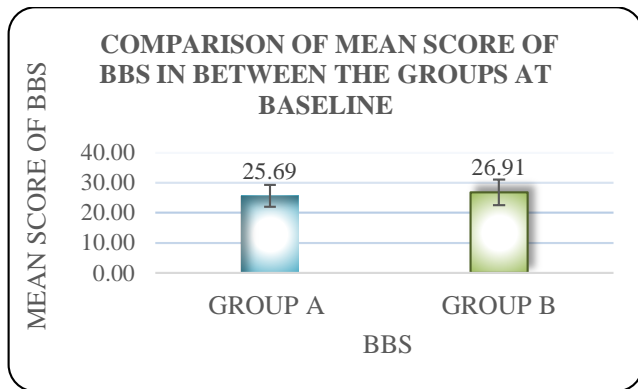
IV. RESULTS AND DISCUSSION

The aim of the study was to identify the effectiveness of Restorative approach and Conventional approach on balance and gait in subjects with Traumatic Brain Injury.

Total 86 subjects with Traumatic brain injury were screened for eligibility, amongst them 73 subjects are included in this study trial. All the 73 subjects who met inclusion criteria have undergone baseline assessment and included subjects were randomised into two equal groups consisting 35 in Group A and 37 in Group B.

In this study, subjects were randomly assigned into 2 groups Group A(Experimental Group) and Group B(Conventional Group), underwent a 30 minute treatment protocol of 5 days per week for 4 weeks duration. In this study, 35 participants completed training

in each group. Comparison of results within the group as well as in between the groups was analysed, evaluation of the intra group and inter group effectiveness of Restorative approach and Conventional approach are under consideration in the present study.



The purpose of the current investigation was to ascertain the impact of restorative strategy versus standard strategy on balance and gait in TBI patients. Numerous studies have demonstrated that TBI is associated with structural white matter changes that involves decreased sensory motor tracks including cerebellar peduncles, posterior thalamic radiation and cortico-spinal track (Roberts et al., 2014). The main objective of the treatment aimed to maximise the sensory motor resources available for the performance of functional mobility skills by means of restorative therapy.²⁵ The goal of restorative approach is to minimise residual disability and to improve functional capacity to level similar to that of pre-morbid functioning. In the present study based on Glasgow coma scale (GCS) only individuals with mild to moderate were included and subjects were screened for balance deficits and gait abnormalities. The following outcome measures Berg Balance Scale and Functional Gait Assessment were used to measure risk of falling due to imbalance and gait respectively.²⁸

The results reveal significant difference between group-A and group-B. Group-A shows statistically more significant improvement in BBS ($p < 0.001$) and FGA ($p < 0.001$). The root driver could be due to task oriented approach prioritised therapeutic measures that are particular to the task being addressed and designed to lesser deficits, maximum optimising, efficient and effective functional regaining techniques for changing the demands as well as environmental concerns in order to reduce residual disability.^{28,29} Researches have shown that goal oriented or skilled learning was associated with cortical reorganisation (Maldonado, et al., 2008; Remphe, et al., 2001). Goal oriented rehabilitation with patient involvement is considered as a key approach to rehabilitation and has been shown to increase patient's satisfaction and adherence in addition individual factors such as self-efficacy and tenacity and motivation have further been identified as potential moderators of goal attainment.^{30,31}

Mechanisms underlying recovery of function after neural injury have been categorised as either restorative (direct) or compensatory (indirect) (Friel and Nudo, 1998). Direct mechanisms involve the resolution of temporary changes and recovery of the injured neural tissue itself. In addition, nearby neural tissue takes over identical neural functions to the original damaged tissue, resulting in restitution of function.³²

Based on extensive review of relevant research on activity-dependent neural plasticity, Klein and Jones (2008) proposed ten principles that potentially influence neuro rehabilitation practices. According to the first principle, "use it or lose it," neuronal circuits that are not actively doing a task for a prolonged amount of time start to deteriorate (This relates to principle 2, "use it and improve it"). However, training preserve neurons and networks that might otherwise be lost following the injury. Principle 3, Neural plasticity is facilitated during practice related to acquisition of skill, not merely repetition of already learned or non-relevant moment. Principle 4, A freshly learnt (or relearned) activity must be repeated in order to cause lasting brain alterations, making repetition a crucial component of neurorehabilitation. Intensity, the fifth principle. Intense training is required to promote experience-dependent brain plasticity. The sixth principle, "Time matters," emphasises that learning and regaining function are processes involving brain plasticity, with later types of plasticity being more frequently depending on those that occur earlier in the process. According to Principle 7, "salience matters"; training must be functionally meaningful and significant in order to optimise activity-dependent brain plasticity to the person. Principle 8, "age matters" training induced plasticity occurs more readily in younger brains. Principle 9, Plasticity in response to one training experience can enhance the acquisition of similar behaviours. Principle 10, plasticity in response to one experience can interfere with the acquisition of other behaviours.^{32,33}

It has been shown that people who have had a TBI exhibit difficulty with dual task while walking even if they have a normal gait speed and it is essential to treat dual task performance for persons with TBI to promote participation in life roles and social functioning. By applying major principles of motor learning during the practice, skill acquisition was facilitated. Motor learning principles included eventual progression from easy exercises to more complicated exercises, variable practice and the use of feedback incorporating both knowledge of results and knowledge of performance.³⁴ These approaches reportedly induce relatively permanent changes in motor behaviour, recognised as learning and it is an indirect evidence that even after the brain injury, the mechanisms of motor learning remain intact (Schmidt and Lee, 2011). When gait was incorporated into dual task paradigms, it was used as the primary task under the assumption that secondary tasks' gait performance reflected the attentional work load of walking devices or changing postural demands during the step cycle.³⁵

It is believed that intrinsic spinal cord circuits can produce locomotor patterns, and that during ambulation supraspinal structures help to maintain the excitatory drive required to activate the spinal locomotor network, to maintain equilibrium, to elicit anticipatory responses, and to create goal directed locomotion. In this study, we sought to gain insights of how this system is regulated under the constraint of concurrent mental and motor demands. Even though walking is a highly practised task, gait parameters related to control of balance are subject to modifications according to attentional demand of concurrent tasks.^{35,36}

It was stated that intervention program using dual task paradigms seem to improve performance in functional tasks of daily life in which divided attention between tasks is required. It is important to emphasize that few clinical trials employing dual task training or multi-modal exercise training suggested that neuronal structural integrity would be preserved and works on physiology and plasticity of neuronal circuits (Smith et.al., 2016; Wollesen and VoelckerRehage, 2019).^{37,38}

On the other hand, group-B also shows significant improvement in Berg Balance Scale (BBS) and Functional Gait Assessment (FGA). The possible evidence shows that the improvement in coordination and performance of gait may be caused by improved proprioception VanNes et al. (2008). In his study reported that preposition of the trunk in response to external perturbations is known as reactive postural control. According to Saeys et al. (2012), enhanced trunk control after trunk control training has a carryover effect on dynamic balance, and the trunk stability is crucial for moving parts.^{39,40}

In terms of comparing the two groups after 4 weeks of intervention program, both the restorative group and conventional group were individually beneficial in reducing imbalance and functional gait performance, when post treatment values of group-A and group-B are compared, findings suggest that restorative approach was more effective than conventional balance training in subjects with TBI. Thus this study concludes that restorative approach as an useful adjuvant therapeutic in improving balance and gait.

These findings, in harmony with a wealth of prior research, emphasis on assessing balance and gait under a variety of motor and motor cognitive conditions using both spatio-temporal and clinical measures should be considered to ensure translatable improvements. Further work should continue to characterise post TBI abnormalities using several issues such as role of gender, age, time since injury and severity of injury as descriptive tools to optimise improvements in targeted sensorimotor outcomes, as well as other goals for impairment, disability and participation.

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