International Journal of Physical Education, Sports and Health 2020; 7(4): 90-97

P-ISSN: 2394-1685
E-ISSN: 2394-1693
Impact Factor (ISRA): 5.38
IJPESH 2020; 7(4): 90-97

www.kheljournal.com
Received: 14-05-2020
Accepted: 16-06-2020

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Effectiveness of stability trainer exercises over conventional physiotherapy on balance re-education in patients with type 2 diabetic peripheral neuropathy

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Abstract
Background: Diabetic peripheral neuropathy (DPN) is relatively common complication of long-term diabetes and is thought to be progressive and irreversible. The loss of sensations associated with Diabetic Peripheral Neuropathy is thought to contribute to impaired balance and increased risk of falling. If the measures of balance are improved, incidence of sustaining falls and injuries can be reduced.
Objective: To determine the effectiveness of Stability Trainer exercises over Conventional Physiotherapeutic exercises on Balance re-education in patients with Type 2 Diabetic Peripheral Neuropathy.
Study Design: Two groups Pre and Post-test Quasi-Experimental study design.
Subjects: 30 patients with Type 2 Diabetic Peripheral Neuropathy aged between 55-65 years both males and females, selected from Diabetic center.
Intervention: Group A received balance training with Stability trainers whereas Group B received Conventional physiotherapeutic exercises.
Outcome Measures: Berg Balance Scale (BBS) and Dynamic Gait Index (DGI) were measured on first day (Week 1) and last day (Week 8) of intervention. Pre-test and post-test scores were compared and results were tabulated.
Results: Both groups showed significant improvement in balance performance. The Group A showed statistically significant improvement in functional balance when compared to Group B (p<0.05).
Conclusion: Balance training on Stability Trainer seems to be beneficial in improving balance in diabetic patients with distal sensory neuropathy.

Keywords: Diabetic peripheral neuropathy, balance, stability trainers.

Introduction
The term Diabetes mellitus describes a metabolic disorder of multiple etiology characterized by hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both [1].
Diabetes mellitus is caused by an insufficient insulin mediated response to blood glucose, people with the disorder classified as Type 1(Beta cell destruction, usually leading to absolute insulin deficiency) or Type 2 (Predominantly insulin resistance with relative insulin deficiency or predominantly insulin secretory defect with or without insulin resistance) diabetes [2].
The World Health Organization (WHO) estimates that nearly 200 million people all over the world suffer from diabetes and this number is likely to be doubled by 2025. India leads the world with largest number of diabetic subjects earning the dubious distinction being termed the "Diabetes capital of the world". At present, confirmed diabetes patients in India are 67 million, with another 30 million in pre diabetes group.
By 2030, India will have the largest number of patients in the world [3].
The classical symptoms of diabetes are Polyuria (frequent urination), Polydipsia (Increased thrust) and Polyphagia (increased hunger). Symptoms may develop rapidly (weeks or months) in Type 1 diabetes while in Type 2 diabetes they usually develop more slowly and may be subtle or absent [2, 4]. Some other diabetic symptoms include Un-usual weight loss, increased fatigue, irritability and blurry vision [5].

Diabetic peripheral neuropathy (DPN) is relatively common complication of long-term diabetes [6] and is thought to be progressive and irreversible [7]. Diabetic Peripheral Neuropathy (DPN) may be characterized by perceived numbness and diminished sensation and/or pain [8].

The common etiological factors causing Diabetic Peripheral Neuropathy (DPN) are Altered Polyol mechanism, Micro-vascular ischemia, reduced levels of Nerve Growth factor (NGF), non-enzymatic protein glycosylation and excessive oxygen free radicals [9]. The pathological changes in Diabetic Peripheral Neuropathy (DPN) include Segmental demyelination, Schwann cell injury and axonal damage [9].

Distal symmetric polyneuropathy is the commonest form of Diabetic neuropathy [10]. It affects men and women with equal frequency [11]. Most peripheral neuropathies damage nerves of the limbs, especially the foot, on both sides and thus lead to balance impairment [12].

The term Postural control and Balance refers to the ability to move efficiently and effectively in a variety of environment without falling. It involves use of many systems to obtain information about the environment and produce appropriate movement and responses. The Visual, Vestibular and Somato-sensory systems relay information about the position and movement of the body, particularly the head in relation to the environment and the position and movement of environment in relation to the body [9].

The Neuromuscular and Musculoskeletal systems allow for voluntarily or reactive motions in response to sensory input. The Cognitive system interprets sensory input to select and coordinate motor output in terms of posture and movement. Changes in any of these contributing systems may result in loss of balance or a fall [9].

In Diabetic neuropathy, there is demyelination of peripheral nerves, injury to the Schwann cells and axonal damage there by involving the three balance controlling systems- visual system, vestibular system and Somato-sensory system and resulting into Postural instability and imbalance [9].

Ageing may also result in impairment of all the three systems along with motor system that are essential for postural control. Older individuals with type 2 diabetes often exhibit greater impairments in posture and gait and are typically at increased risk of falling [13, 14].

A switch over from Ankle based to Hip based balance strategy [9].

In patients with diabetes, regular participation in physical activity can improve glycaemic control and reduce cardiovascular mortality [15, 16]. Exercise that improves lower-extremity balance and strength (force-generating capacity) has been shown to be effective in reducing falls in older adults [17, 21]. If the measures of balance are improved, incidence of sustaining falls and injuries can be reduced.

Conventional Physiotherapeutic exercises for Diabetic Peripheral Neuropathy (DPN) includes, Range of motion exercises for bilateral lower limbs. Lower limb strengthening exercises. Functional Balance exercises. Wobble Board Training. Gait Training including Single leg standing &Tandem walking.

Foot Care & other Preventive measures

Balance training is commonly provided by Balance pads, Balance disc and pods, Rocker boards, Core stability disks, Foam rollers, Multi slant board etc. Recently Stability

Trainers are gaining popularity in improving balance in patients with Diabetic Peripheral Neuropathy (DPN).

Stability Trainers are oval shaped colour coded pads, available in three densities

Green with smaller surface area and firm density, Blue with larger surface area and soft density and Black with air filled inflatable extra soft pad.

Levels of challenge are determined by an increasing order of instability. A fixed set of exercises are designed to perform on Stability Trainer [22].

Balancing on foam reduces the use of somatosensory inputs of the ankles for controlling balance, thereby challenging visual and vestibular inputs for balance control [23, 24]. The present study was conducted to investigate the effectiveness of this concept in diabetic patients with Diabetic Peripheral Neuropathy (DPN). If found effective, it can be used as a simple, cost effective training in improving the balance of Diabetic Peripheral Neuropathic patients.

Methodology

The study was conducted in: Diabetic Medicare centre, T-nagar and Diabetes. By using convenient sampling method 30 subjects were taken from Diabetic Medical Centre, Chennai. After briefing the procedure, Information sheet was given and informed consent was taken. Subjects with the age between 55-65 years, Both female and male Patients with a diagnosis of Type 2 Diabetes with Diabetic Peripheral Neuropathy based on nerve conduction studies more than 50 meters/seconds. Berg Balance Scale Score between (35-45 out of 56). Dynamic Gait Index Score more than (19 out of 24). Patients with moderate neuropathy according to TORANTO clinical neuropathy score (9-11 out of 14). Fasting blood sugar within 130 – 200 mg / dl consistently for at least 6 month on stable medications. Ability to complete three minute walk test. Ability to make unipedal stance for 20 seconds was included. Those subjects with evidence of plantar ulcers and foot problems. Any vestibular disorder. History of any known Cardio respiratory Complications. History of any Orthopaedic Complications. History of any other Neurologic Complications. Peripheral vascular complications. Body Mass Index above 30. Any Hearing and Visual defects were excluded

Study Design: Quasi-Experimental.
Study Type: Pre-test and Post-test study.
Sample Size: 30 samples. Experimental Group – 15, Control Group - 15
Sampling Method: Convenient sampling
Study Duration: 2 months

Procedure

The subjects who came for treatment in Diabetic Medicare Centre and Diabetic Medical Centre were assessed with a detailed history and diabetic evaluation. The subjects were assessed according to the Assessment chart (Annexure 2) and who satisfied the inclusion criteria were included in the study. They were informed about the study procedure in detail and an informed consent form was obtained.

Prior to the intervention Vital signs including Pulse Rate, Temperature, Respiratory Rate and Blood Pressure were recorded as a precautionary measure. If the vitals were not stable, the patient was advised not to do the exercises for the day.

Prior to the procedure, subjects were assessed for the following Pre-test baseline measures. Berg balance scale (BBS). Dynamic Gait Index (DGI)

Among 78 subjects, 30 subjects were selected and

conveniently divided into two groups (15 subjects each)
Group A (Experimental Group) received the Conventional Physiotherapeutic Exercises and Balance training with Stability Trainers.
Group B (Control Group) received the Conventional Physiotherapeutic Exercises.

S. No.	Intervention for group A	Intervention for group B
1.	Relaxed deep breathing exercises (3 minutes)	Relaxed deep breathing exercises (3 minutes)
2.	Range of Motion exercises for bilateral Ankle joints (5 minutes)	Range of Motion exercises for bilateral Ankle joints (5 minutes)
3.	Functional balance training (15 minutes)	Functional balance training (15 minutes)
	Sit to stand (5 times) Standing weight shifts (5 times each) Functional reach sideward & forward for touching targets set by the therapist (5 times each) Bipedal heel rise for 20 seconds (5 times each) Unipedal standing 15 seconds (5 times each) Unipedal standing with knee bending 15 seconds (5 times each)	Sit to stand (5 times) Standing weight shifts (5 times each) Functional reach sideward & forward for touching targets set by the therapist (5 times each) Bipedal heel rise for 20 seconds (5 times each) Unipedal standing 15 seconds (5 times each) Unipedal standing with knee bending 15 seconds (5 times each)
4.	Balance training in Stability trainers (Green, Blue, Black)(15 minutes) Levels of challenge were increased by increasing the order of instability Each level was practiced for 4 sessions 1.Bipedal heel rise for 20 seconds (5 times) 2.One leg balance for 15 seconds (5 times each) 3.Hip flexion for 15 seconds (5 times each) 4.Hip extension for 15 seconds (5 times each) 5.Knee flexion up to 90 degree for 15 seconds (5 times each)	Balance training in Wobble board (15 minutes)
5.	Gait training Tandem walking (5 minutes) Spot marching (5 minutes)	Gait training Tandem walking (5 minutes) Spot marching (5 minutes)
Total Time	60 minutes with 1 minute rest for every 5 minutes of exercise.	60 minutes with 1-minute rest for every 5 minutes of exercise.

After allocating the subjects in Experimental group & Control Group, the Interventions were provided twice weekly for 8 weeks, with two days rest in between each session. Interventions were provided during the morning session after their medications.
Patients in both groups were assessed with the Berg Balance Scale & Dynamic Gait Index following the treatment (Last day Week 8) and Pre-test and Post-test scores were used for statistical analysis

Outcome Measures
Berg Balance Scale: Berg Balance Scale (BBS) is an objective measure of balance abilities. This tool relates to meaningful activities of daily living like sit to stand, variations in standing positions, transfer, turning and other balance activities.
The scale consists of 14 functional tasks commonly performed in everyday life. Scoring uses a five-point ordinal scale, with scores ranging from
0-4. (41)

Dynamic Gait Index: The Dynamic Gait Index (DGI) was developed to assess walking under various dynamic conditions. The scale consists of 8 common gait tasks, walking on a level surface, changing gait speed, walking with vertical and horizontal head turns, pivot turning, stepping over an obstacle, and ascending/descending stairs. Each item is scored (0-3), lower scores indicating greater impairment [41]

Statistical Analysis
The statistical tools used in this study are Paired't'-test and Independent't'- test. These are commonly used for comparing two groups.
The 't'-test is used to compare two means, and see if the difference between the two-sample means is significant.
The Independent't'-test is used to compare difference between two groups whereas Paired 't'-test is used to compare difference between pre-test and post-test values within the same group.
The formula for Independent 't'-test:

$$t = \frac{X_1 - X_2}{S.E}$$

$$S = \frac{\sqrt{(n_1 - 1) + (n_2 - 1)s^2}}{n_1 + n_2 - 2}$$

$$S.E = \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}$$

Where,
n_1 sample size in group A n_2 sample size in group B
S_1^2 the square of standard deviation of 1st group
S_2^2 the square of standard deviation of 2nd group
X_1 mean value of first group
X_2 mean value of second group
The formula for the paired t-test is given by:

$$t = \frac{\Sigma d}{\sqrt{\frac{n(\Sigma d^2) - (\Sigma d)^2}{n-1}}}$$

The top of the formula is the sum of the differences (i.e. the

sum of *d*). The bottom of the formula reads as:
The square root of the following: n times the sum of the differences squared minus the sum of the squared differences, all over n-1.

- The sum of the squared differences: $\sum d^2$ means take each difference in turn, square it, and add up all those squared numbers.
- The sum of the differences squared: $(\sum d)^2$ means add up all the differences and square the result. Data Analysis Table
- Statistical tabulation to analyze the comparison of pre and post values of Berg Balance Scale (BBS) in GROUP Ausing Paired T-Test.

Table 1: Statistical tabulation to analyze the comparison of pre and post values of Berg Balance Scale (BBS) in GROUP A using Paired t-Test.

S. No.	Grade	Mean	Standard Deviation	t-Value	Significance Level
1	Pre – BBS Score (Total)	39.00	3.13	-19.20	0.00
2	Post – BBS Score (Total)	48.53	3.56		

p<0.05

In Table 1, p is less than 0.05, which shows that there is a significant difference between pre-test and post-test values of Berg Balance Scale (BBS) Scores in Group A subjects trained with Stability trainers.

Table 2: Statistical tabulation to analyze the comparison of pre and post values of Berg Balance Scale (BBS) in GROUP B using Paired t-Test.

S. No.	Grade	Mean	Standard Deviation	t-Value	Significance Level
1	Pre – BBS Score (Total)	39.86	3.24	-13.28	0.00
2	Post – BBS Score (Total)	44.33	3.10		

p<0.05

In Table 2, p is less than 0.05, which shows that there is a significant difference between pre- test and post-test values of Berg Balance Scale (BBS) Scores in Group B subjects trained with Conventional Physiotherapeutic exercises.

Table 3: Statistical tabulation to analyze the comparison of pre and post values of Dynamic Gait Index (DGI) in Group Ausing Paired t-Test.

S. No.	Grade	Mean	Standard Deviation	t-Value	Significance Level
1	Pre – DGI Score (Total)	20.26	1.38	-7.29	0.00
2	Post – DGI Score (Total)	22.13	0.83		

p<0.05

In Table 3, p is less than 0.05 which shows that there is a significant difference between pre-test and post-test values of Dynamic Gait Index (DGI) Scores in Group A subjects trained with Stability trainer.

Table 4: Statistical tabulation to analyze the comparison of pre and post values of Dynamic Gait Index (DGI) in Group B using Paired t-Test.

S. No.	Grade	Mean	Standard Deviation	t-Value	Significance Level
1	Pre – DGI Score (Total)	20.06	0.883	-6.95	0.00
2	Post – DGI Score (Total)	21.13	0.915		

p<0.05

In Table 4, p is less than 0.05, which shows that there is a significant difference between pre-test and post-test values of Dynamic Gait Index (DGI) Scores in Group B subjects trained with Conventional Physiotherapeutic exercises.

Table 5: Statistical tabulation to analyze the comparison of post-test values of Berg Balance Scale (BBS) between Group A and Group B using Independent t- Test.

S. No.	Groups	Mean (BBS)	Standard Deviation (BBS)	t-Value	Significance
1.	Group A	48.53	3.56	3.440	0.002
2.	Group B	44.33	3.10		

p<0.05

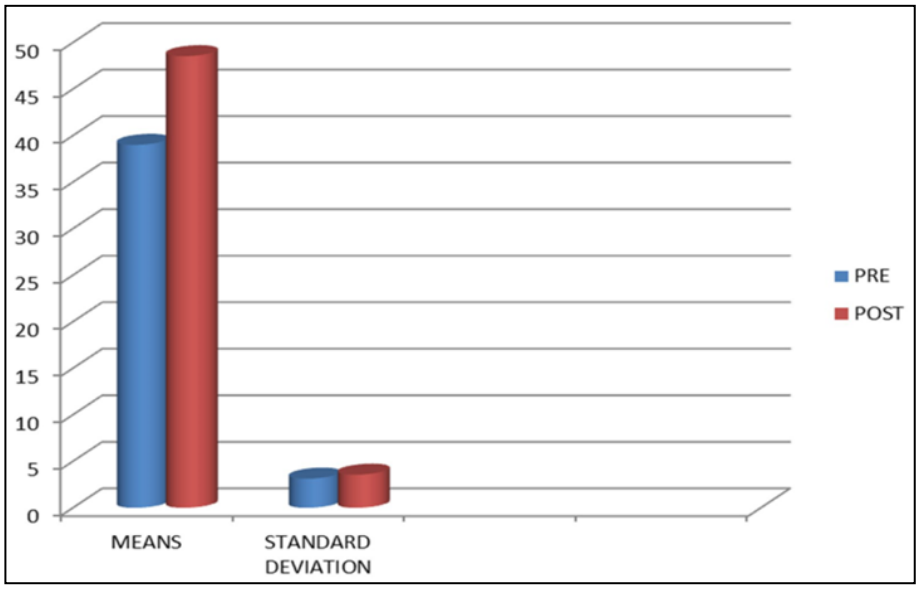
In Table 5, p is less than 0.05, which shows that there is a significant difference in Berg Balance Scale (BBS) Scores between Group A subjects trained with Stability trainers and Group B subjects trained with Conventional Physiotherapeutic exercises.

Table 6: Statistical tabulation to analyze the comparison of post-test values of Dynamic Gait Index (DGI) between Group A and Group B using Independent t-Test.

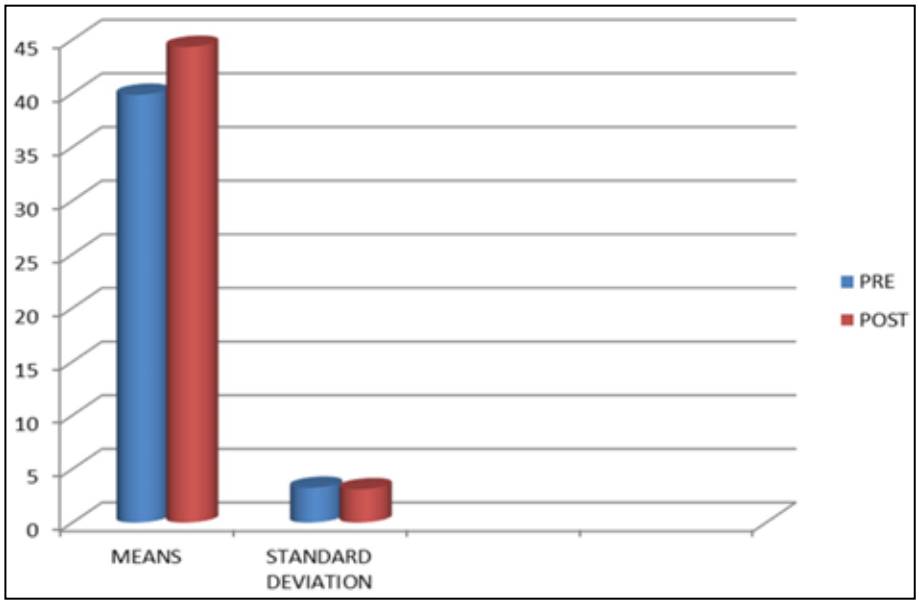
S. No.	Groups	Mean (DGI)	Standard Deviation (DGI)	t-Value	Significance
1.	Group A	22.13	0.83	3.125	0.002
2.	Group B	21.13	0.91		

p<0.05

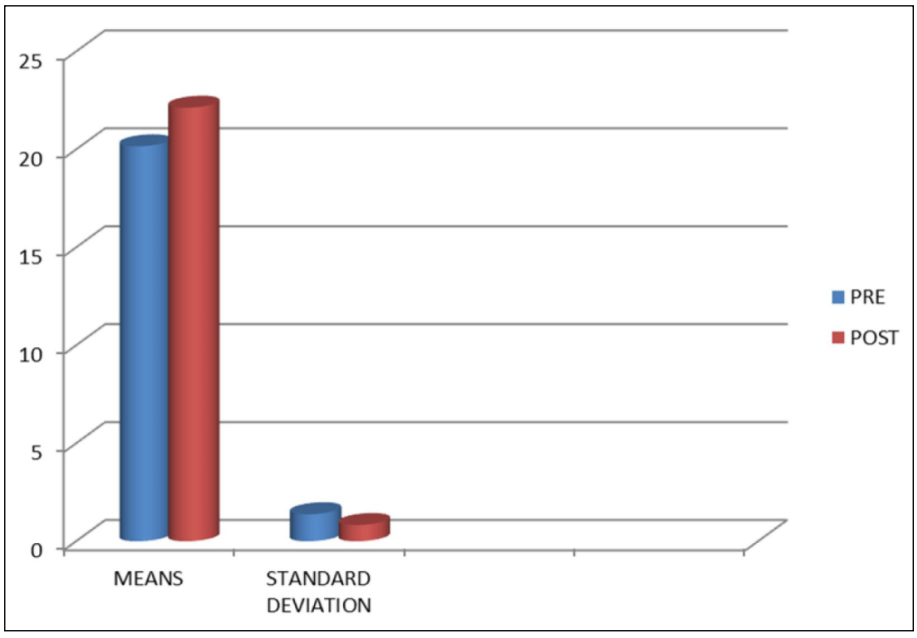
In Table 6, p is less than 0.05, which shows that there is a significant difference in Dynamic Gait Index (DGI) Scores between Group A subjects trained with Stability trainers and Group B subjects trained with Conventional Physiotherapeutic exercises.



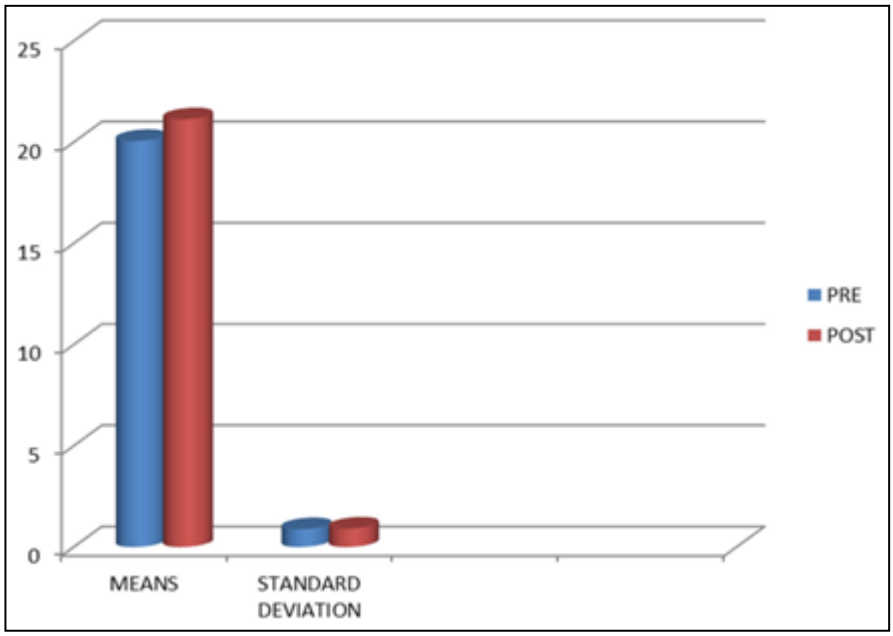
Graph 1: Bar Graph showing comparison of pre-test values and post-test values of Berg Balance Scale (BBS) in Group A



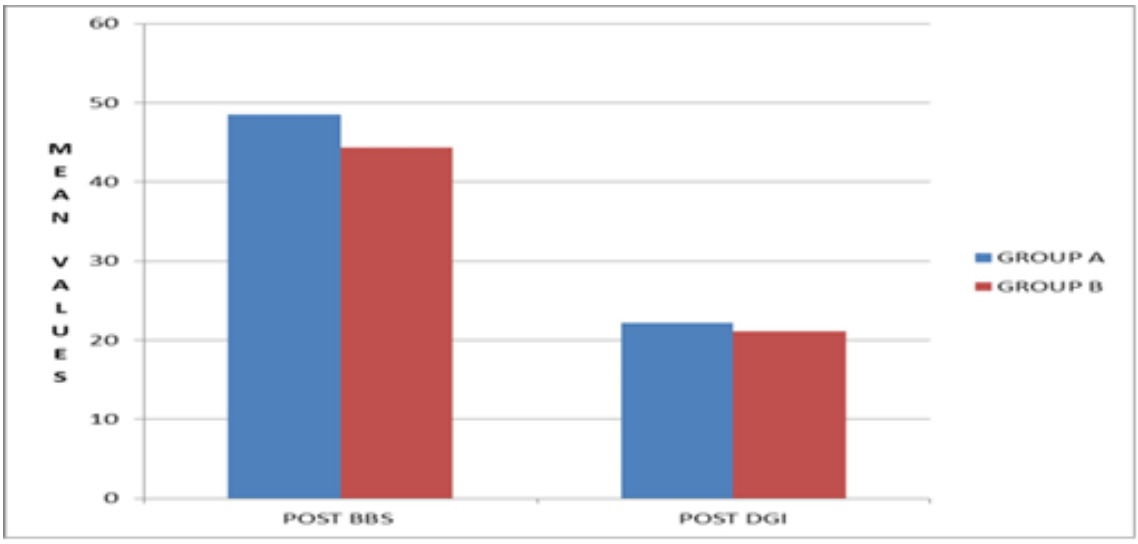
Graph 2: Bar Graph showing comparison of pre-test and post-test values of Berg Balance Scale (BBS) in Group B.



Graph 3: Bar Graph showing comparison of pre-test and post-test values of Dynamic Gait Index (DGI) in Group A.



Graph 4: Bar Graph showing comparison of pre-test and post-test values of Dynamic Gait Index (DGI) in Group B.



Graph 5: Bar Graph showing comparison of post-test values of Berg Balance Scale (BBS) and Dynamic Gait Index (DGI) in Group A and Group B.

Discussion

The study focused on to determine the Effectiveness of Stability trainer exercises in Diabetic patients with Balance impairment. Diabetic Peripheral Neuropathy is the most common complication of long-term Diabetes causing diminished sensations thus leads to balance impairment. Providing patients with specific balance training may improve balance as well as decrease the risk of fall in them. Horak FB *et al.* (2001), found that Diabetic patients with peripheral neuropathy have significant loss of ankle movement perception and have larger ranges of postural sway [35]. Tofthagen C *et al.* (2012), from their review study founded substantial evidence to support the use of strength and balance training for older adults at risk for falls and individuals with peripheral neuropathy [26]. Balance exercise program improved balance and trunk proprioception in individuals with diabetic neuropathy [28]. Since many years various balance training programs were used. Thus the objective of this study is to determine the Effectiveness of Stability trainer exercises over Conventional physiotherapeutic exercises on Balance re-education in patients with Diabetic Peripheral Neuropathy. The results of the study has proved that both Group A subjects trained with Stability trainers and Group B subjects trained with Conventional Physiotherapeutic exercises had shown a statistically significant improvement in Berg Balance Scale (BBS) and Dynamic Gait Index (DGI) values post 8 weeks training. This could be because both Stability trainers and Wobble board provides unstable surface there by challenging the balance. The statistical results of this study shows that there is a clinically significant increase in Berg Balance Scale (BBS) and Dynamic Gait Index (DGI) values in Group A subjects trained with Stability trainers for a period of 8 weeks (p<0.05). This result goes in hand with, M.S. Ajimisha *et al.* (2011), who concluded that there was a significant improvement in balance, with Stability trainers [22]. Based on above study, the present study also proves the effectiveness of Stability trainer exercises in improving balance in patients with Diabetic Peripheral Neuropathy. Stability Trainer provides an unsteady surface that challenges the body to maintain balance. During the exercise intervention with Stability Trainer, sensory inputs were manipulated by altering the support surface and environments. The

improvement in Berg Balance Scale (BBS) and Dynamic Gait Index (DGI) values in Group A subjects trained with Stability trainers could be because of Unstable surface, Continuous sensory input, and Proprioceptive firing from receptors of the foot thus involving the Visual system, Vestibular system as well as Somatosensory Balance controlling systems improving balance and postural control there by reducing the risk of falls. It also provides the subjects with three progressive levels, further challenging the somatosensory system for balance. Michael ER *et al.* (2005) found that Balance training in progressive challenging levels can enhance somatosensory integration with visual and vestibular senses in Central Nervous System [36]. Kelly PW (2007) and Phil P. (2006) found evidence of similarly enhanced central integration, following sensory training, demonstrating improved stability during the manipulation of proprioceptive, vestibular or all of these, by use of Sensory Organization Test (SOT) [37-38]. Fay BH (2010) also reported that Somatosensory training using Stability Trainer can also augment increased proprioceptive firing from the cutaneous receptors from the feet and also from mechanoreceptors of the muscle during co-contraction produced by the swaying movement, while standing on Stability Trainer [39-40]. Thus balance training with Stability trainers can be used as a simple and cost effective treatment program in improving balance in patients with Diabetic Peripheral Neuropathy.

Conclusion

This study focused to determine the effectiveness of balance training with Stability trainers over Conventional Physiotherapeutic exercises in patients with Diabetic Peripheral Neuropathy.

The results of the study indicates that there is a statistically significant difference between Group A subjects trained with Stability trainers and Group B subjects trained with Conventional Physiotherapeutic exercises.

The study concluded that Group A subjects trained with Stability trainers showed more clinically significant improvement in Berg Balance Scale (BBS) and Dynamic Gait Index (DGI) values. Thus balance training on Stability Trainers will be significantly more effective than the regular Conventional Physiotherapy exercises in improving balance in patients with Diabetic Peripheral Neuropathy.

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