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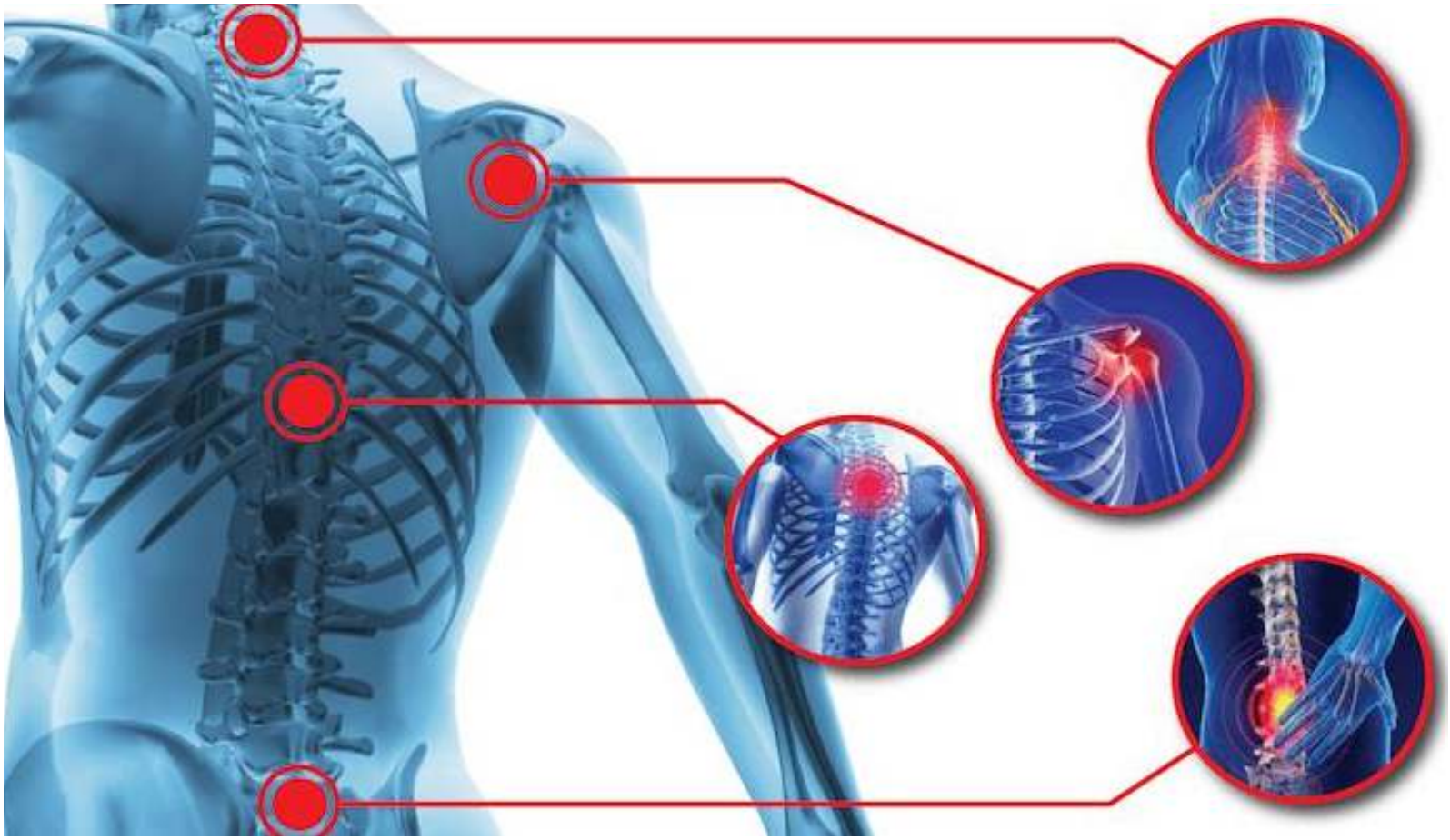

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EFFECTS OF ACTIVE VIBRATION TRAINING COMBINED WITH BALANCE TRAINING ON BALANCE, BALANCE CONFIDENCE AND FEAR OF FALL IN SUBJECTS WITH DIABETIC PERIPHERAL NEUROPATHY – A QUASI EXPERIMENTAL STUDY

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ABSTRACT

Introduction: Diabetes can lead to long-term complications, including peripheral neuropathy in which sensation diminishes in extremities due to nerve damage, reduce awareness of joint position and movement sense leading to loss of balance, postural

instability, decreased confidence in performing daily living activities and overall quality of life.

Primary Objective: To elevate effects of active vibration training and Balance training on Balance, Fall risk and Balance Confidence in Diabetic Peripheral Neuropathy patients.

Methodology: Thirty patients with Diabetic Peripheral Neuropathy were randomly assigned to experimental A (n=15) and Control B (n=15) groups. The group A performed active vibration training using flexi-bar along with balance training and Group B received balance training for a duration of 6 weeks. Both the groups were assessed at the baseline, 3rd week and after 6 weeks. Outcome measures were Ortho-king Pressure Plate SDP610 (Postural Sway), Activities Specific Balance Confidence, Modified Fall Efficacy Scale.

Results: The study revealed that combining Active Vibration with balance training significantly improves balance. Group A showed marked improvements in postural sway (AP direction), balance confidence (ABC), and reduced fall risk (MFES) over 6 weeks. Key p-values (≤ 0.001) highlight strong statistical significance, confirming the added effectiveness of Active Vibration in enhancing balance and safety.

Conclusion: On the basis of results, active vibration exercise effectively improved Postural Deviation, balance confidence and decreased the fall of risk in diabetic peripheral neuropathy patients.

Keywords: Active Vibration Training, Balance, Diabetes, Flexi-Bar, Polyneuropathy.

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1. INTRODUCTION

Diabetes Mellitus is a complicated metabolic condition which has characteristics of increased glucose levels in blood (hyperglycemia), which results from abnormality in either secretion of insulin or its action on the body and results in dysfunction of fat, protein and carbohydrate's

metabolism. The pattern of progression of diabetes is complex and has irregular or variable presentation.[1] Diabetes mellitus is a major global health issue, which may lead to Diabetic peripheral neuropathy (DNP) which common complication that can cause nerve damage, muscle weakness and mobility problems. Exercise training may help alleviate DPN symptoms and this explores its effects on physical function and muscle strength in people with DPN.[2] Diabetes mellitus is a complex metabolic disorder marked by high blood sugar levels, resulting from defects in insulin secretion or action. This condition leads to a range of complications, including damage to organs such as the eyes, kidneys, heart and nerves. Prolonged high blood sugar levels can cause microvascular and macrovascular problems, leading to issues like retinopathy, nephropathy and neuropathy. These complications can result in serious health problems, including blindness, kidney failure and cardiovascular disease. Diabetes also increases the risk of foot infections, ulcers and amputations, as well as cardiovascular disease, which is a major cause of diabetes-related illness and death. Type 2 diabetes is the most common form of diabetes, accounting for 90-95% of cases. It's defined by two main issues: insulin resistance, where cells become less sensitive to insulin and β-cell dysfunction, where β-cells initially overproduce insulin to compensate.[3]

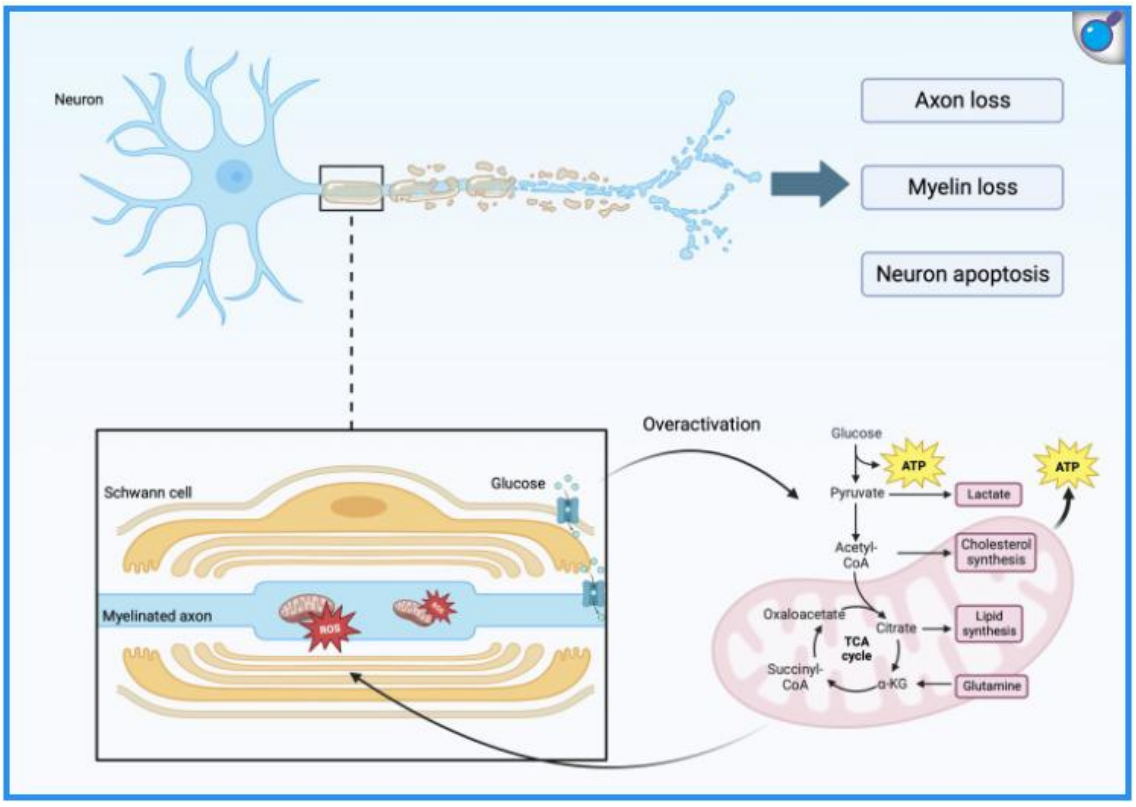

Figure 1 Axonal myelin sheath injury.[4]

Individuals with diabetes are more prone to balance disorders and dizziness due to potential damage to these systems caused by prolonged hyperglycemia. Balance is a complex skill that requires the integration of multiple sensorimotor and cognitive processes. The somatosensory, visual and vestibular systems all contribute to balance control. Vestibular dysfunction increases with age and is more prevalent among people with diabetes mellitus.[5] Diabetic peripheral neuropathy increases fall risk due to muscle weakness, balance impairment and fear of falling. This study explores whether lower balance confidence is associated with higher fall risk among DPN patients.[6] Diabetic neuropathy and vascular disease are serious complications of diabetes. While diabetic microvascular complications are well-studied, early detection of diabetic neuropathy remains poorly understood. Diabetic peripheral neuropathy affects up to 50% of individuals with diabetes and its incidence increases with diabetes duration. DPN can lead to biomechanical abnormalities, increasing the risk of falls and diabetic foot problems. This study explores whether early-stage DPN, diagnosed by nerve conduction study, can influence biomechanical parameters, such as gait and balance, using wearable wireless sensor systems and electrophysiological devices. The Flexi-Bar is a 153 cm vibrating exercise tool that provides an innovative way to engage in exercises that promote muscle coordination and balance. Its active vibration technology allows users to control the speed and amplitude of the vibrations, engaging their muscles in a dynamic and challenging workout. Flexi-Bar exercises have been shown to be effective in improving trunk muscle thickness and balance, and can be a valuable tool for rehabilitation and fitness training.[8]

Subjects and Methodology

Study Design The research design executed in the current study was of quasi-experimental type in which convenient sampling method was used in order to fulfill the objective of activity specific balance, postural deviations, modified fall efficacy scale among patients with diabetic peripheral neuropathy. The patients enrolled in the study were 30 adults between the age of 45-65 with the study duration of 6 week.

2. PROCEDURE:

The patients meeting the inclusion criteria were recruited for the study and divided into two groups where Group A received active vibration training along with balance training and Group B

received only balance training. After obtaining the consent, patients were assessed according to the criteria of Michigan Neuropathy Screening Instrument. Detection of protective sensation (or to determine the loss of protective threshold) were performed using the standard procedure for 5.07/10 g Semmes Weinstein Monofilament Test and assessment of vibration sense were done using Tuning Fork (128Hz).

Experimental Group – The Experimental group performed total 5 sets of exercises in which 1 set comprised of 30 sec vibrations followed by 90 sec rest for 10 minutes a day and five times a week for a period of 6 weeks using a flexi bar.

Before the intervention training, patient had 3 trials for one week to get familiar with flexi-bar use. An active vibration exercise workout using flexi-bar for the training was performed in the following pose. The patient stood with feet shoulder width apart and held flexi-bar with the dominant hand with shoulder flexed to 90 degrees, the patient performed the antero-posterior vibration exercise. The patients were instructed to activate the Flexi-bar at the highest frequency possible. After 5 minutes rest, patient performed balance training. Balance Training involved conventional balance exercises targeting static and dynamic balance which included warm-up exercises consisted Stretching, Sensory ball massaging, Step up and down on foam for 10 minutes and Balance exercises which included Standing exercise on stable surface for 4 min/set ,Heel and toe raise , One-leg stance for each limb and after this rest was given by Sitting on the Thera ball with legs supported and Weight shifts-forward and backward, Upper extremity Thera-Band exercises, Standing exercises on foam for 4 min/set, which included weight shifting forward, backward, sidewards and diagonal One-leg stance for each limb were performed and then rest was given by Sitting on the Thera ball, legs supported and forward and backward weight shifts, Upper extremity Thera-Band exercises. Progressive balance exercises for 4 min/set were performed - Passing football while standing on foam in a circle, Throwing and catching ball standing on the trampoline Throwing and catching ball on foam and then Cool-down exercise which involved Deep breathing exercises, abdominal breathing exercises, static abdominals were performed.

Fig 1. Flexi-bar, trampoline ball catching and throwing, sensory ball massage, Thera-ball and Thera-Band exercises.

Control group –Balance Training involved conventional balance exercises targeting static and dynamic balance. Warm-up exercise in which stretching, sensory ball massaging, step up and down on foam for 10 mins were performed after this balance exercise which involved standing exercise on stable surface for 4 min/set, Heel and toe raise, One-leg stance for each limb was performed. Rest was given by sitting on the Thera ball with legs supported, weight shifts-forward and backward, Upper extremity Thera-Band exercises were done. After rest period, standing exercises on foam for 4 min/set. Standing on foam with Weight shifting forward, backward, sidewards and diagonal One-leg stance for each limb was performed. Rest was given by Sitting on the Thera ball with legs supported, Weight shifts-forward and backward, Upper extremity Thera-Band exercises were performed. Progressive balance exercises for 4 min/set - Passing football standing on foam in a circle, Throwing and catching ball standing on the trampoline Throwing and catching ball on foam, Cool-down exercise - Deep breathing exercises, abdominal breathing exercises, static abdominals.

Duration of the Study: 6 weeks (30 samples had been collected for the study between January 10, 2024, and February 21,2024.)

Result

Data Analysis

Group A included 11 males and 4 females, while Group B had 7 males and 8 females. The mean age was 55.27 ± 6.14 years in Group A and 54.20 ± 5.58 years in Group B ($p = 0.62$), and the

mean BMI was 27.85 ± 4.07 kg/m² and 26.61 ± 3.53 kg/m² in Groups A and B, respectively ($p = 0.38$) Show in table 1.

Table 1. Demographic characteristics of the patients.

	GA(n-15)	GB(n-15)	p value
Gender(M/F)	11/4	7/8	-
Age(year)	55.27±6.14	54.20±5.58	0.62
BMI	27.85±4.07	26.61±3.53	0.38

The within-group analysis for Group A (Experimental Group) receiving Active Vibration Training combined with Balance Training using Repeated ANOVA revealed a significant improvement in Postural Deviation in the Antero-Posterior (AP) direction with eyes open (EO) over the intervention period. The mean difference and SD scores of postural deviations from day 1- 5.27±2.58 to week 3 - 3.39±2.31 and from week 3 to week 6- 2.06±0.820 indicating improved Postural Deviation shown in table no.2.The F-test value was 26.02, indicating a strong effect, and the p-value (0.001) confirmed statistically significant difference. These findings highlight the positive impact of AVT combined with BT in enhancing balance control in patients with DPN shown in table no. 3.

Group B analysis has shown a significant change in Postural Deviation in the Antero Posterior Direction (Eyes Open - EO) over time. The mean postural deviation decreases from 4.92 mm on Day 1 to 4.73 mm at Week 3 and further to 4.51 mm at Week 6. This suggests that postural control improves over time with the intervention. The S.D. decreases from 2.03 (Day 1) to 1.90 (Week 3) to 1.79 (Week 6), indicating reduced variability in postural deviation, meaning participants' responses become more consistent. The mean difference and SD scores of postural deviations from Day 1- 4.92±2.03 to Week 3 - 4.73±1.90, from week 3 to Week 6 - 4.51± 1.79 indicating improved postural deviation shown in table no. 2. The F-Test = 6.75 indicates that the between-timepoint differences are meaningful. P-value = 0.004, which is less than 0.05, confirms that the reduction in postural deviation is statistically significant shown in table no.3.

Table 2. Mean differences over the weeks in outcome measures between Group A(GA) and Group B(GB)

Mean	Group A			Group B		
	Day 1	Week 3	Week 6	Day 1	Week 3	Week 6
PD (EO)	5.27± 2.58	3.39± 2.31	2.06± 0.82	4.92± 2.03	4.73± 1.90	4.51± 1.79
ABC (Score)	62.79±6.64	71.75±6.74	82.38±5.78	64.75±2.88	67.53±4.83	70.76±7.86
MFES (Score)	6.24± 0.29	7.20± 0.43	8.27± 0.44	6.47± 0.47	6.80± 0.95	6.93± 1.11

Group A shows a significant improvement in Balance Confidence over time ($p < 0.05$). The F-test value of 273.6 indicates strong statistical significance shown in table no. 3. The increase in mean and SD scores from 62.79±6.64 at Day 1 to 71.75±6.74 at Week 3 and further to 82.38±5.78 at Week 6 suggests that active vibration and balance training effectively enhance Balance Confidence in Type 2 Diabetes Mellitus patients with peripheral neuropathy shown in table no. 2.

Group B using Repeated Measures ANOVA shows a significant improvement in Balance Confidence over time. The F-test value of 8.36 indicates strong statistical significance shown in table no. 3. The Activities-Specific Balance Confidence (ABC) Scale (%) Mean and SD Scores shows an increasing trend from 64.75±2.88 (Day 1) to 67.53±4.83 (Week 3) to 70.76±7.86 (Week 6), indicating improvement. There is a significant effect of time on ABC Scale scores in Group B, suggesting that the Active Vibration Training Combined with Balance Training led to improved balance confidence over six weeks shown in table no. 2.

Table 3. Comparison of F test to table value within the groups

	Group	T Value	F test	P Value
PD (EO)	GA	3.34	26.02	0.001
	GB	3.34	6.75	0.004
ABC(Score)	GA	3.34	273.6	0.001
	GB	3.34	8.36	0.001
MFES (Score)	GA	3.34	281.5	0.001
	GB	3.34	3.16	0.058

Values represented as Mean+SD; PD: Postural Deviation, GA: Group A, GB: Group B, EO: Eyes Open. *$p < 0.05$.

Group A shows a significant improvement in the Modified Falls Efficacy Scale over time (from Day 1 to Week 6). The F-test value of 281.5 indicates strong statistical significance table no.3. There is a progressive increase in the mean and SD scores from 6.24±0.29 (Day 1) to 7.20±0.43 (Week 3) to 8.27±0.44 (Week 6), indicating improved balance confidence shown in table no.2.The results suggest a significant improvement in balance confidence over time in Group A, likely due to the intervention. If the P-value is actually <0.001 (instead of 3.34), it confirms a statically significant change over time.

Group B indicate that the Modified Falls Efficacy Scale did not show statistically significant changes over time. mean and SD scores from 6.47±0.47 (Day 1) to 6.80±0.95(Week 3) to 6.93±1.11 (Week 6), indicating improved balance confidence shown in table no.2. However, P-Value of 0.058 (Table Value =3.34) might be the significance threshold (alpha = 0.05), meaning the p-value is above the significance level. The F-test value (3.16) suggests some variance across time points. Since the result is "Not Significant," the changes in Modified Falls Efficacy Scale from Day 1 to Week 6 are not statistically meaningful shown in table no. 3.

The effect of Active Vibration Training along with Balance Training on postural deviation in the antero-posterior direction (eyes open) across different time points (Day 1, Week 3, and Week 6) between Group A and Group B. The mean Postural deviation in Antero Posterior and SD score in from slightly higher in Group A 5.27±2.58 than Group B 4.92±2.03(Day1), Group A shows a greater reduction in Postural Deviation Mean and SD from 3.39±2.31 compared to Group B Mean and SD from 4.73 ±1.90 (Week 3) and Group A mean and SD from 2.06±0.82 improves more than Group B Mean and SD from 4.51±1.79(Week 6) as shown in table no. 4. Since $P < 0.05$, this result is statistically significant, confirming that Group A shows greater improvement over time. While both groups showed Postural Deviation improvement over time, statically significant difference with p value =0.001 was achieved only on the Week 6. The unpaired T test value for the Day 1 and week 3 assessment (p=0.6853 and p=0.0924 respectively) indicate that initial improvements where not statically significant shown in table no.5.

The effect of Active Vibration Training along with Balance Training on Activities-Specific Balance Confidence (ABC) Scale across different time points (Day 1, Week 3, and Week 6) between Group A and Group B. The mean ABC and SD score in from slightly higher in Group B 64.75±2.88 than Group A 62.79±6.64 (Day1), Group A shows a greater reduction in ABC Mean and SD from 71.75±6.74 compared to Group B Mean and SD from 67.53 ±4.83 (Week 3) and

Group A mean and SD from 82.38±5.78 improves more than Group B Mean and SD from 70.76±7.86(Week 6) shown in table no. 4. Since $P < 0.05$, this result is statistically significant, confirming that Group A shows greater improvement over time. While both groups showed ABC improvement over time, statical significant (p=0.001) was achieved only on the Week 6. The unpaired T test value for the Day 1 and week 3 assessment (p=0.3039 and p=0.0584 respectively) indicate that initial improvements where not statically significant shown in table no.5. The significant result at Week 6 supports the hypothesis that vibration training enhances balance confidence in patients with diabetic peripheral neuropathy. By Week 6, Group A showed a significantly greater improvement in balance confidence compared to Group B.

The mean± SD score for the modified falls efficacy Scale across the different time point (Day 1, Week 3, and Week 6) between Group A and Group B. The mean MFES and SD score in from slightly higher in Group B 6.47±0.47 than Group A 6.24±0.29 (Day1), Group A shows a greater reduction in ABC Mean and SD from 7.20± 0.43 compared to Group B Mean and SD from 6.80±0.95(Week 3) and Group A mean and SD from 8.27±0.44 improves more than Group B Mean and SD from 6.93±1.11(Week 6) shown in table no.4. While both groups showed balance improvement over time, statistically significant difference ($p = 0.001$) was achieved only on the week 6th shown in table no.4. The unpaired t-test value for the day 1 and week 3 assessments ($p = 0.1120$ and $p = 0.1389$, respectively) indicate that initial improvements were not statistically significant shown in table no.5. This suggests that while active vibration training and balance training may have an impact, a longer intervention period might be necessary to achieve clinically meaningful changes.

Table 4. Mean differences over the weeks in outcome measures between Group A(GA) and Group B(GB)

Mean	Day 1		Week 3		Week 6	
	Group A	Group B	Group A	Group B	Group A	Group B
PD (EO)	5.27±2.58	4.92± 2.03	3.39± 2.31	4.73± 1.90	2.06± 0.82	4.51± 1.79
ABC (Score)	62.79±6.64	64.75±2.88	71.75±6.74	67.53±4.83	82.38±5.78	70.76±7.86
MFES (Score)	6.24± 0.29	6.47± 0.47	7.20± 0.43	6.80± 0.95	8.27± 0.44	6.93± 1.11

Table 5. Comparison of unpaired T test to table value between the groups

	Unpaired T test (score)			P value			Table value
	Day 1	Week 3	Week 6	Day 1	Week 3	Week 6	
PD	0.409	1.742	4.832	0.685	0.092	0.001	2.05
ABC Score	1.047	1.973	4.611	0.3039	0.0584	0.0011	2.05
MEFS Score	1.641	1.523	4.341	0.1120	0.1389	0.0012	2.05

Values represented as Mean ±SD; PD: Postural Deviation, GA: Group A, GB: Group B, EO: Eyes Open. $p < 0.05$.

3. DISCUSSION

Holmes CJ et al[2] Diabetes Mellitus is one of the most prevalent metabolic diseases both in developing and developed nations. Long-Term diabetes causes a series of pathologies associated with nerves, vascular and lymphatic system and can cause neuropathy. DPN is the most complication associated with DM and damages motor as well as sensory nerves of upper and lower limbs due to elevation of glucose levels in blood from a long time. Additionally, it causes pain, muscle atrophy along with fat infiltration, altered or diminished sensations and muscle dysfunction in extremities. The damage sustained by motor and sensory nerves leads to impairment of muscle fiber nerve and blood supply causing atrophy of muscles and impairments of balance making the patient prone to falls. In the present study we found that 4 weeks of Active Vibration Training using Flexi-bar along with Balance training improved balance, risk of fall and balance confidence in patients with diabetic peripheral neuropathy. Our study results showed statistically significant differences in balance, risk of fall and balance confidence measured using Ortho king Pressure Plate, Modified Falls Efficacy Scale and Activities Specific Balance Confidence Scale respectively. A study by Um KM et al[9] was conducted to see the effect of a 6-week long flexi-bar exercises on balance and postural alignment in subjects with asymmetric posture discussed that the vibration produced by flexi bar is quite low in frequency (5 Hz) and this frequency is transmitted through the hand to other body parts although none of the studies have proven or quantified this claim. In a study by Mileva KN et al[10] it has been proven that Flexi-bar transmits or spreads the low frequency vibration stimulus from upper limb to trunk and then to lower limb in single leg squat position. The

possible reason behind improvement in balance could be due to that the vibration produced by Flexi-bar stimulates proprioceptors thereby generating a strong sense of joint movement which is induced by external load imposed by intense stimulation. The postural/tonic muscles of abdomen, waist and pelvic regions improve lumbar stability and postural control and thereby play an important role in improving balance and stability. A study conducted by Chung JS et al[11] aimed to investigate and compare the effects of flexi-bar and non-flexi-bar exercises on the activation of trunk musculature in 3 different postures which were quadruped, side bridging and standing. Different muscles were assessed for the activation by the method of EMG namely Rectus abdominis, Erector spinae, External oblique and Internal oblique. Out of all the 3 postures; the flexi bar exercises performed in standing position generated a greater muscle activity in the external oblique, as in this position patients had to maintain the trunk in a narrow base of support. A study conducted by Seo DK et al[12] demonstrated that inner muscles of abdomen are responsible for providing stability to lumbopelvic region during Functional movement. The results of our study cannot be directly linked with existing literature as none of the studies have been conducted to evaluate the effect of Flexi-bar training on balance confidence and risk of fall but there are several observational studies conducted to find an association between these two parameters and balance impairment. One such study conducted by Riandini T et al[13] aimed at investigating the association between risk of fall and balance confidence among subjects with diabetes induced neuropathy. The authors observed that balance confidence; assessed using total ABC was inversely proportional to fall risk, meaning, an improved balance confidence was associated with a reduced incidence of falls and fall risk. The reduced confidence in maintaining balance and the fear of fall markedly limits one's ability to perform daily functional activities. This contributes to deconditioning and ultimately to increased disability and loss of function or ability to perform activities independently, which could increase chances of falling. Other studies have also reported that diabetes and diabetes related neuropathy is linked to impairments of balance and consequently increased fall risk. Individuals who are affected from diabetes for a longer duration of time have shown to be associated with weak muscles and increased incidence of hospitalization due to increased events of falling. According to a study conducted by Richardson JK et al[14] balance exercises performed for 3 weeks helped in improving both Static and dynamic balance and also activities specific balance confidence in the older subjects. Therefore, the existing literature review shows that none of the studies have been conducted in subjects with DPN for improving balance confidence and

reducing risk of falls. Thus, our study is the first study to target balance confidence and fall risk directly. The results of our study demonstrated that Flexi-bar exercises combined with conventional balance exercises helps in improving the balance confidence and reduces the risk of fall in subjects with DPN. Another study by Winter DA et al[15] observed similar improvements in diabetic population by 27.43%. it has been proposed that the improvement in A-P sway might be because the subjects had to use ankle strategy to maintain their balance. The A-P sway is improved by ankle strategy.

4. FUTURE SCOPE

Difficulty in generalizing the results as the sample size is small, future studies with larger sample size are required, long term effects of exercising with flexi bar are unknown, therefore future studies are warranted to investigate whether the changes induced by flexi-bar training are long lasting or not. Lack of randomization or blindness may have led to selection bias, future studies conducted with true blindness may prevent selection and treatment assignment bias. There was an absence of control group without any treatment protocol and an experimental group with flexi-bar training alone.

5. CLINICAL IMPLICATION

The study showed that there is a decrease in postural sway (in AP direction), peak and average postural sway in DM Type 2 patients with polyneuropathy. Therefore, in clinical practice postural sway should be assessed in all patients with polyneuropathy for early identification.

6. CONCLUSION

This study was carried out to find out the comparison between the efficacy of flexi bar combined with balance exercises and the effect of balance exercises alone on balance, balance confidence and risk of fall. Our study showed that both exercises improved the patient outcomes, However, combining the Flex-bar exercises with conventional balance exercises proved to be superior and produced better results. Exercising with Flexi-bar is safe and produce low vibrational excitations and can be used easily without any supervision. The improvement in patient outcomes

could be achieved in short treatment duration as compared to conventional balance training that needs longer training periods.

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