"Effects of Gait Training versus Proprioceptive Neuromuscular Facilitation on Balance and Gait in Diabetic Neuropathy: a Randomized Clinical Trial"

Maryam Rauf [1], Sabiha Arshad[1], Sumera Abdul Hameed[1]
[1] Department of Rehabilitation and Allied Health Sciences, Riphah International University, Gulberg campus, Lahore, Pakistan

Abstract:

Background: Diabetic neuropathy is one of the major complications of diabetes mellitus, which mainly affects lower limbs in patients with diabetes. Thus, taking into consideration, the debilitating effects of diabetic neuropathy, is advocated for these individuals to prevent further deterioration. There is meager literature supporting the effectiveness of proprioceptive neuromuscular facilitation (PNF) in individuals with diabetic neuropathy.

Objective: The purpose of the study was to compare the effects of gait training exercises and proprioceptive neuromuscular facilitation on balance and gait in diabetic neuropathic individuals.

Method: A total of 40 diabetic patients were randomly allocated into two groups. Group I (Gait Training Exercise Group) and Group II (PNF Group). The study was conducted for 8 weeks. The subjects followed up with a therapist for a 30-minute session twice a week. Each participant underwent a clinical evaluation on the Dynamic Gait Index (DGI), Berg balance scale (BBS), Tinetti, and at day 1 and the end of the 8th week.

Result: The result showed that both the Gait training exercises and PNF were effective in improving the gait and balance of diabetic neuropathy patients. After eight weeks of intervention, there was a statistically significant difference between the gait training and PNF treatment group based on the scores of BBS, $p = 0.02$. There was no statistically significant difference between the scores of TT of the gait training group and PNF treatment group $p = 0.07$. Based on the scores of DGI, there was a statistically significant difference between of gait training group and the PNF treatment group

Conclusion: PNF is more effective than Gait training in improving the clinical measures of balance and gait in patients with diabetic neuropathy.

Keywords: Balance, Diabetic neuropathy, Exercise, Functional Training, Type 2 diabetes

Introduction:

Diabetes Mellitus is a metabolic disorder that results from a defect in insulin secretion, insulin action, or both. [1] A major consequence of Diabetes Mellitus is diabetic peripheral neuropathy (DPN) which is associated with higher mortality rates, lower limb amputations in particular, and distressingly painful neuropathic symptoms.[2] DPN can affect almost half the population of people with diabetes depending on the age of the patient and onset of diabetes.[3]

Neuropathic symptoms due to Diabetes can be sensory-motor or both. Sensory symptoms include tingling, numbness, tightness, scorching or burning pain, and sensory ataxia. While motor symptoms include muscle stiffness, weakness, atrophy, and balance impairments.[4] All these symptoms interfere with a person's daily activities and ultimately compromise their quality of life.[5]

The sensory, motor, and autonomic control system is altered by DPN, which impacts the quantity and quality of sensory information used to generate and regulate gait.[6] Moreover, the lack of protective sensation and intrinsic foot dysfunction due to DPN also contributes to altered gait.[3,7] Due to changes in gait mechanics, muscle strength, and restricted range of motion, patients with DPN experience decreased mobility and are at an increased risk of falling.[8-12]

Other significant symptoms in persons with DPN include postural instability and gait disruption.[13] To walk normally and maintain postural stability, the musculoskeletal, cerebrovascular, vestibular, and neurological systems must coordinate in a complex multimodal manner. In patients with DPN several abnormalities including sensory loss, reduced muscle strength alterations in the central nervous system contribute to impaired postural stability and gait in patients with diabetes

Various exercise therapies have been employed to reduce gait and balance abnormalities and enhance functional capacity for patients suffering from diabetic neuropathy. Exercise interventions such as Swiss ball exercises, balance training, endurance training, and strength training all play a part in managing the difficulties of diabetic neuropathy.[14] In diabetic neuropathy, strengthening lower limbs in functional positions can result in quicker foot reaction times to visual cues, improved leg strength, less sway, and a decreased risk of falling.[15]

The awareness of joint and body movements as well as the orientation of the body or body segments in space is known as proprioception which is impaired in diabetes. Proprioceptive neuromuscular facilitation (PNF) is one of the therapeutic approaches that take proprioceptive stimuli into account. Evidence is present in which PNF is utilized as a technique in attempting to improve function, particularly in individuals with several disorders that cause gait and balance impairments including cerebral palsy, multiple sclerosis, stroke, and diabetic neuropathy. PNF concentrates on enhancing patients' mobility and stability, strengthening, coordinating, and controlling their movements. It also helps in improving endurance through the facilitation of proprioceptors.[16]

Gait training exercises are interventions to optimize and enhance walking performance in diabetic neuropathic individuals by eliciting voluntary activation in key muscle groups, increased coordination and muscle strength, increased velocity and endurance, increased flexibility, and preventing adaptive changes in lower limb soft tissues.[16,17] These interventions may help improve the gait and balance in diabetic peripheral neuropathy patients.[5]

Proprioceptive neuromuscular facilitation (PNF) are routine interventions that mimic daily life's movements and use proprioceptive stimuli to improve movement control, coordination, and strength by establishing adequate balance between stability and mobility while also enhancing endurance through proprioceptor facilitation. [5,18] It is the therapeutic intervention developed by Herman Kabat which is habituated to facilitate an individual's presentation with motion deficiency.[19]

Proprioceptive neuromuscular facilitation intervention exercises assist significant muscle bundles of the lower limbs in diabetic patients affected by peripheral neuropathy by enhancing their generation of strength and power while they are walking. These interventions can hopefully help diabetic neuropathic patients amplify and strengthen the weakened flexors/extensors and ankle plantar flexors. [20]

Since the evidence available for the effect of proprioceptive neuromuscular facilitation (PNF) and gait training exercises in patients with diabetic neuropathy is deficient, the two interventions are compared in this study, namely proprioceptive neuromuscular facilitation (PNF) and gait training exercises to compare their effects in improving parameters of balance and gait in these neuropathic individuals so that risk of falls can be reduced and functional quality of life can be improved and to determine which intervention is better suited for these patients.[5]

The majority of the studies have focused on sensory and motor manifestations including neuropathic pain but studies that quantitatively analyze the gait and posture in patients with DPN using objective measurement tools are less. The objective of this study was to analyze gait and posture quantitatively in patients with DPN and to determine the effects of PNF and gait training exercises on balance and gait in diabetic neuropathy patients and compare them.

Methodology:

Study Design

This study was a randomized clinical trial. Patients were recruited from the Central Park Teaching Hospital, Lahore, Pakistan after being diagnosed with diabetic neuropathy and experiencing significant balance disorder. Patients were assessed for eligibility and consented. Eligible participants were randomly assigned to either receive gait training or PNF using a random number generator.

Participants

A total of 50 patients suffering from diabetic neuropathy were assessed for eligibility. 08 participants were excluded for not meeting the inclusion criteria and 02 did not consent to take part in the study. 40 participants (23 males, and 17 females) were included in this study. All the participants provided written informed consent before the beginning of assessments or interventions.

Participants were included in the study if they were diagnosed with Diabetes Mellitus (DM) type 1 or type 2, suffering from balance disorders, gait instability, or paresthesia in the lower limb for at least the past three months, with a score of more than 7 in the Michigan Neuropathy screening instrument and required assistance with walking. The exclusion criteria included the presence of any musculoskeletal conditions such as muscle sprains, strains or tears, arthritis, fracture of the lower limb in the past six months imbalance due to vestibular dysfunction or ear infection, amputation, or presence of any active skin infection of legs or feet.

Intervention

The interventions were given to the patients by a trained physiotherapist who remained close to the patients to avoid falls or injury.

Gait training

The first group of 20 participants received gait training for eight weeks. It involved the performance of various exercises. The exercises were performed twice a week for a total of eight weeks. On each day the exercises were performed in three sets with breaks in between. Each set took about 30 minutes with breaks in between the different types of exercises. On each day the

whole session lasted for around a total of 90 minutes. The following exercises were performed three times within each set:

1. The first exercise was one-foot balancing where the patients were asked to stand with feet hip-width apart and to distribute equal weight on both legs while placing their hands on their hips. Once the starting position was achieved; the patients were asked to lift one leg off the floor and bend it back towards the knee while the weight-bearing knee straightened. This position was to be maintained for 30 seconds either with or without support. This exercise was then repeated by the other leg. Most of the participants experienced difficulty in maintaining this position, therefore they were asked to hold a chair or support while performing the exercises.
2. The second exercise was leg raises performed in the standing position by abducting the leg out to 45 degrees and holding it there for five seconds. The participants were asked to take support from a chair by holding it with the contralateral arm.
3. The third exercise as part of advanced gait training, was heel raises which were performed by lifting the heels off the floor. The participants were asked to to start with the feet flat on the floor and then to point the toes towards the floor while lifting the heels off the floor. For this exercise the participants were asked to take support from a chair placed in front of them.
4. The final exercise as part of gait training was the practice of tightrope walking performed between parallel bars. This involved abducting the arms while trying to walk in a straight path. This was a challenging task for the patients with severe balance impairments, therefore they were allowed to take some support from the parallel bars while walking.

Proprioceptive Neuromuscular Facilitation

Proprioceptive Neuromuscular Facilitation (PNF) was performed in the patterns of diagonal movement. The first PNF pattern of diagonal movement was performed in the diagonal 1 (D1) flexion and extension pattern whereas the second pattern was performed in the diagonal 2 (D2) flexion and extension pattern. Different techniques of PNF were combined in this study including hold-relax, contract-relax, hold-relax-contract, and rhythmic stabilization. All the techniques were performed in a single pattern and then these techniques were repeated in the remaining three patterns. PNF was performed three times with each technique and in each pattern three times on each side in a single set. Each set had a duration of 30 to 40 minutes. PNF was performed in three sets each day. This intervention was given to patients with diabetic neuropathy twice a week for eight weeks.

Outcome measures

The primary outcome measure was the Berg balance scale (BBS). BBS is used to quantitatively evaluate the functional balance in patients with balance disorders. It is a reliable, valid and sensitive to change scale, which includes 14 items with a maximum score of 56. The score reflects the patient's ability to control postural balance where higher scores are indicative of good balance.

The secondary outcome measures were the Tinetti assessment test (TT) and Dynamic Gait Index (DGI).

TT is a task-performance exam. The scoring is performed on a three-point ordinal scale with a range of 0 to 2. A score of 0 represents the most impairment, while a score of 2 represents

independence. The individual scores are then combined to form three measures; an overall gait assessment score, an overall balance assessment score, and a combined gait and balance score. The maximum score for the gait component is 12 points. The maximum score for the balance component is 16 points. The maximum total score is 28 points. In general, residents who score below 19 are at high risk for falls.

DGI is a test used to assess the likelihood of falling in older adults. Scoring is performed on a four-point ordinal scale, ranging from 0-3 where "0" indicates the lowest level of function and "3" is the highest level of function. The total score is 24 and a score less than 19 is predictive of falls in the elderly.

Data Analysis

All obtained data was analyzed with the Statistical Package for Social Science (SPSS) version 29 program. Before data analysis, the data were tested for normal distribution using the Shapiro-Wilk normality test, and homogeneity of variance was measured using Levene's test. Since the data was distributed normally, repeated measures ANOVA (RM-ANOVA) was used for within-group analysis, and an independent t-test was used for between-group comparisons. RM-ANOVA for pairwise comparison with Bonferroni correction was used to compare the difference in scores of BBS, TT and DGI after four and eight weeks of intervention from the scores recorded at baseline. Between-group comparisons were performed at baseline to determine if there was any significant difference between the scores of the two groups before the initiation of intervention. Between group analyses were repeated at the mid-treatment time point after four weeks of intervention and at the post-treatment time point after eight weeks of intervention. Results were presented as mean and standard deviation (SD). Probability values that were less than 5% ($p<0.05$) were considered as statistically significant.

Result:

The mean MNSI score of the 20 patients in the group of patients who received gait training, was 11.5. There were 11 males and 9 females in this group. The mean MNSI score was 10.3 of the 20 patients in the group of patients who received PNF. There were 12 males and 8 females in this group (Table 1).

Table 1:

Participants Number	Group 1 (Gait Training)		Group 2 (PNF)	
	Gender	MNSI score	Gender	MNSI score
P1	M	9	M	8
P2	M	13	M	10
P3	M	15	M	15
P4	M	11	M	11
P5	F	8	F	8
P6	F	9	M	11
P7	F	11	F	10
P8	F	14	F	13
P9	M	11	F	9
P10	M	12	F	10
P11	F	8	M	8
P12	M	10	M	12

P13	M	12	M	11
P14	M	12	F	8
P15	M	15	M	9
P16	F	13	F	10
P17	M	15	F	14
P18	F	11	M	12
P19	F	9	M	8
P20	F	12	M	9

Table 1 Demographic data of participants of group 1 who received gait training and group 2 who received PNF. M = Male, F = Female, MNSI = Michigan neuropathy screening instrument

WITHIN-GROUP ANALYSIS

Gait Training Group:

Effects of 8 weeks of gait training on balance based on BBS

Repeated measures ANOVA was conducted to evaluate the effects of eight weeks of gait training on balance assessed using the Berg balance scale. The eight-week gait training had a statistically significant effect on balance, $F(2, 18) = 177.08$, $p < .001$. The analyses were followed by pairwise comparison with confidence interval adjustment by Bonferroni correction. The pairwise comparison revealed a significant effect of gait training on balance between pre-and post-treatment, $p < 0.001$, 95 % confidence interval (CI) = -10.91 - -8.29. The pairwise comparison also revealed a significant effect of gait training on balance over four weeks between pre- and mid-treatment $p < 0.001$, 95 % CI = -5.31 - -3.59.

Effects of 8 weeks of gait training on gait and balance based on TT

Repeated measures ANOVA was conducted to evaluate the effects of eight weeks of gait training on gait and balance assessed using the Tinetti test. The eight-week gait training had a statistically significant effect on gait and balance, $F(2, 18) = 447.92$, $p < .001$. The analyses were followed by pairwise comparison with confidence interval adjustment by Bonferroni correction. The pairwise comparison revealed a significant effect of gait training on gait and balance between pre-and post-treatment, $p < 0.001$, 95 % confidence interval (CI) = -4.56 - -3.84. The pairwise comparison also revealed a significant effect of gait training on gait and balance over four weeks between pre- and mid-treatment $p < 0.001$, 95 % CI = -2.35 - -1.55.

Effects of 8 weeks of gait training on risk of fall based on DGI

Repeated measures ANOVA was conducted to evaluate the effects of eight weeks of gait training on the risk of falls assessed using the dynamic gait index test. The eight-week gait training had a statistically significant effect on gait and balance, $F(2, 18) = 135.36$, $p < .001$. The analyses were followed by pairwise comparison with confidence interval adjustment by Bonferroni correction. The pairwise comparison revealed a significant effect of gait training on gait and balance between pre-and post-treatment, $p < 0.001$, 95 % confidence interval (CI) = -4.24 - -3.16. The pairwise comparison also revealed a significant effect of gait training on gait and balance over four weeks between pre- and mid-treatment $p < 0.001$, 95 % CI = -2.35 - -1.55.

PNF Group:

Effects of 8 weeks of PNF on balance based on BBS

Repeated measures ANOVA was conducted to evaluate the effects of eight weeks of PNF on balance assessed using the Berg balance scale. The eight-week PNF treatment had a statistically significant effect on balance, $F(2, 18) = 172.15$, $p < .001$. The analyses were followed by pairwise comparison with confidence interval adjustment by Bonferroni correction. The pairwise comparison revealed a significant effect of PNF treatment on balance between pre-and post-treatment, $p < 0.001$, 95 % confidence interval (CI) = -17.69 - -13.41. The pairwise comparison also revealed the significant effect of PNF treatment on balance over four weeks between pre- and mid-treatment $p < 0.001$, 95 % CI = -9.04 - -6.56.

Effects of 8 weeks of PNF on gait and balance based on TT

Repeated measures ANOVA was conducted to evaluate the effects of eight weeks of PNF treatment on gait and balance assessed using the Tinetti test. The eight-week PNF treatment had a statistically significant effect on gait and balance, $F(2, 18) = 139.52$, $p < .001$. The analyses were followed by pairwise comparison with confidence interval adjustment by Bonferroni correction. The pairwise comparison revealed a significant effect of PNF treatment on gait and balance between pre-and post-treatment, $p < 0.001$, 95 % confidence interval (CI) = -5.32 - -3.88. The pairwise comparison also revealed the significant effect of PNF treatment on gait and balance over four weeks between pre- and mid-treatment $p < 0.001$, 95 % CI = -2.84 - -1.76.

Effects of 8 weeks of PNF on the risk of fall based on DGI

Repeated measures ANOVA was conducted to evaluate the effects of eight weeks of PNF treatment on the risk of falls assessed using the dynamic gait index test. The eight-week PNF treatment had a statistically significant effect on gait and balance, $F(2,18) = 212.33$, $p < .001$. The analyses were followed by pairwise comparison with confidence interval adjustment by Bonferroni correction. The pairwise comparison revealed a significant effect of PNF treatment on gait and balance between pre-and post-treatment, $p < 0.001$, 95 % confidence interval (CI) = -5.57 - -4.33. The pairwise comparison also revealed the significant effect of PNF treatment on gait and balance over four weeks between pre- and mid-treatment $p < 0.001$, 95 % CI = -2.98 - -2.05.

BETWEEN-GROUP ANALYSES

At baseline, the two treatment groups had no statistically significant difference.

After four weeks of intervention, there was a statistically significant difference between the gait training and PNF treatment group based on the scores of BBS, $t(38) = -2.6$, $p = 0.13$. There was no statistically significant difference between the scores of TT of the gait training group and the PNF treatment group, $t(38) = -1.857$, $p = 0.071$. There was no statistically significant difference between the scores of DGI in the gait training group and the PNF treatment group, $t(38) = -1.56$, $p = 1.27$.

After eight weeks of intervention, there was a statistically significant difference between the gait training and PNF treatment group based on the scores of BBS, $t(38) = -3.39$, $p = 0.02$. There was no statistically significant difference between the scores of TT of the gait training group and the PNF treatment group, $t(38) = -1.86$, $p = 0.07$. Based on the scores of DGI, there was a statistically significant difference between of gait training group and the PNF treatment group, $t(38) = -2.11$, $p = 0.041$.

Table 2:

Intervention	Time point	BBS	TT	DGI
Gait training	Pre-treatment	25.55 ± 4.94	6.45 ± 2.19	9.65 ± 3.01
	Mid-treatment	30 ± 5.53*	8.4 ± 2.26*	11.6 ± 3.15*
	Post-treatment	35.15 ± 5.94*	10.65 ± 2.32*	13.35 ± 3.33*
PNF	Pre-treatment	27.45 ± 5.61	7.5 ± 2.56	10.8 ± 3.33
	Mid-treatment	35.25 ± 7.16* #	9.8 ± 2.5*	13.3 ± 3.71*
	Post-treatment	43 ± 8.47* &	12.1 ± 2.59*	15.75 ± 3.84* &

Data are presented as mean ± SD

- * Significantly different from baseline
- # Significantly different from mid-treatment scores of gait training
- & Significantly different from post-treatment scores of gait training

Discussion:

Several studies have assessed the effects of gait training and PNF intervention individually on balance and gait in the patients of diabetic neuropathy but to the best of the author's knowledge, no study has compared the effects of these interventions.

The results of this study showed that balance and gait are improved with a reduction in the risk of falls in patients with diabetic neuropathy after four weeks of gait training and PNF intervention. The scores of BBS, TT and DGI improved further in the next four weeks in both gait training and PNF intervention groups. When comparing the results between both groups it was observed that after four weeks, the score of BBS improved significantly higher in patients receiving PNF than the patients receiving gait training. Similarly, after eight weeks, it was observed that patients PNF were more effective in improving balance and reducing the risk of falls compared to gait training according to the results of BBS and DGI in patients with diabetic neuropathy. Both gait training and PNF intervention were effective in improving gait according to the results of TT in patients with diabetic neuropathy.

These results are supported by the findings of Allet et al. which revealed that 12 weeks of specific gait training and balance exercises improved gait in diabetic patients.[21] Another trial conducted by the authors revealed that 12 weeks of balance and gait exercises combined with function-orientated strengthening improved balance, mobility, lower limb strength, and fear of falling in diabetic patients.[22] A follow-up conducted 6 months after the end of the 12-week intervention period showed that balance, mobility, and fear of falling were significantly better than their scores at baseline.[22] A focused exercise regimen including uni pedal and bipedal toe and heel raises and inversion and eversion exercises performed over the period of three weeks improved balance in patients with diabetic neuropathy.[23]

Another study by Taveggia et al. reported that four weeks of multimodal balance, gait training and strengthening exercises significantly improved gait endurance in diabetic patients compared to the standard care group after a period of four weeks. However, the authors reported that this treatment regimen was ineffective in improving gait speed of diabetic patients after four weeks. Moreover, both the multimodal approach and standard care interventions were equally effective in improving function in diabetic patients according to the scores of functional independence measure. A two-month follow up after the intervention period showed that the gait endurance remained

significantly improved compared to baseline in diabetic patients compared to the standard care group.[24]

PNF on the other hand, is an integration of strength, stretching and flexibility components. These components are essential for the maintenance of balance. PNF activates the proprioceptors located in the joints, tendons and ligaments which leads to improvement in motor function, flexibility and balance.[25]

Current study results also demonstrated that PNF improved gait and balance and reduced the risk of falling after four and eight weeks of intervention. In older adults with history of fall, PNF intervention was administered for 12 sessions over the period of four weeks to assess gait components and compared to older adults who performed general exercise over the same time period. It was reported that PNF intervention was significantly more effective in improving various components of gait and reducing the risk of falling in future in older adults compared to the general exercise group.[26] Our results are in line with the results of a study by Al-Ahmari et al. as well who reported that PNF stretching of ankle plantar flexors for four weeks resulted in the improvement of balance in patients who had ankle sprain.[27] Moreover, PNF has been demonstrated to be superior to weight training in improving athletic performance by enhancing muscle strength of lower limb muscles.[28]

It was observed that at four weeks or at eight weeks there is no significant difference between the scores of TT in the gait training and PNF intervention group although the means scores were higher in the PNF intervention group. This could be due to the combined results reported of the gait and balance assessment scores. As the results of the BBS and DGI scores indicate that PNF is significantly more effective in improving balance than gait training, it might have improved the balance assessment scores of the TT compared to the gait assessment scores. This suggests that both gait training and PNF intervention are effective in improving gait.

There are a few studies that have evaluated the effects of gait training and PNF alone on balance and gait in patients with diabetic neuropathy. However, to the best of our knowledge, this is the first study that compared the effects of gait training and PNF on balance and gait in patients with diabetic neuropathy. The results of this study have demonstrated that gait training and PNF are effective in improving balance and gait which may help clinicians in devising effective rehabilitation protocols in patients suffering from diabetic peripheral neuropathy.

However, this study has a few limitations. This study did not include a control group or sham intervention to compare the results of intervention group due to time constraints. The intervention was only given for a period of eight weeks and the long-term effects of these interventions were not assessed. For this study, a combination of different PNF techniques was used and the effects of individual techniques were not compared with the effects of gait training. Further studies are required to understand the long-term effects of these interventions by conducting follow-up assessments after three to six months. Moreover, Future studies are warranted that explore the combined effects of both interventions.

Conclusion:

Both gait training and PNF intervention were effective in improving balance and gait and reducing risk of falls in patients with diabetic peripheral neuropathy. However, PNF was significantly more effective in improving balance after four and eight weeks of intervention compared to gait training.

Furthermore, PNF was significantly more effective in reducing the likelihood of falling in elderly patients with diabetic neuropathy after eight weeks of intervention compared to eight weeks of gait training.

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Authors Detail

First Author: Maryam Rauf
Student, at Department of Rehabilitation and Allied Health Sciences, Riphah International University, Gulberg campus, Lahore, Pakistan
Second Author: Sabiha Arshad
Senior Lecturer / Physiotherapist, at Department of Rehabilitation and Allied Health Sciences, Riphah International University, Gulberg campus, Lahore, Pakistan
Third Author: Sumera Abdul Hameed
Senior Lecturer, at Department of Rehabilitation and Allied Health Sciences, Riphah International University, Gulberg campus, Lahore, Pakistan

Corresponding author: Sabiha Arshad