

## Effect of Ankle Proprioceptive Training on Gait and Risk of Fall in Patients With Diabetic Neuropathy: A Randomized Controlled Trial

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### ABSTRACT

**BACKGROUND:** Alterations in gait characteristics and falls are common symptoms in patients with diabetic neuropathy. However, little is known about possible treatment strategies for improving gait ability and reduce risk of fall in patients with diabetic neuropathy.

**PURPOSE:** This study was conducted to investigate the effect of ankle proprioceptive training on gait and risk of falling in patients with diabetic neuropathy.

**METHODS:** Thirty patients with diabetic neuropathy from both sexes, their ages ranged from 50-65 years were randomly assigned to study or a control group. The study group ( $n = 15$ ) received ankle proprioceptive training in addition to traditional physical therapy

exercises, whereas the control group ( $n = 15$ ) received traditional physical therapy exercises only, three sessions a week for eight weeks. Spatiotemporal gait parameters (Walking velocity (cm/sec), step length of dominant limb (cm), step time (sec), cadence (step/min) and double support time (sec) and risk of falling were assessed for all patients in both groups before and after the treatment program.

**RESULTS:** There was no significant difference between both groups in the pre-treatment mean values of all measured variables. Significant improvement was observed in the two groups between pre and post treatment measured outcomes. Furthermore, the study group recorded significantly better improvement in all measured variables compared with the control group.

**CONCLUSION:** Ankle proprioceptive training could be an excellent supplement to traditional physical therapy exercises used for improving gait and reducing risk of falling in patients with diabetic neuropathy.

**Key words:** Ankle proprioceptive training; Gait; Fall risk; Diabetic neuropathy

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### INTRODUCTION

Diabetic peripheral neuropathy (DPN) is a common chronic complication of diabetes mellitus which results in high public health costs and has a huge impact on patients' quality of life<sup>[1]</sup>. It leads to sensory and motor deficits, which often result in mobility-related dysfunction, balance impairments<sup>[2]</sup>, and alterations in gait characteristics<sup>[3]</sup>. These alternations in gait performance cause increase in the risk of fall, which has the strongest association with symptoms of depression in patients with diabetes<sup>[4]</sup>.

Gait in DPN is known as a conservative gait performance, that occurs with high double support time, slow speed, and shorter steps

as an attempt to keep stability in walking<sup>[5,6]</sup>. It has been reported by Goldberg *et al*<sup>[7]</sup> that, 39 % of patients with DPN take more than 10 sec during unilateral leg stance. Also, Allet *et al*<sup>[8]</sup> showed that, diabetic patients with polyneuropathy have more gait alterations than diabetic patients without polyneuropathy. These alternation in gait characteristics is closely related to impairment in ankle proprioception<sup>[9]</sup>.

Many authors have found that individuals with diabetes and peripheral neuropathy demonstrate impaired ankle joint movement perception<sup>[10-12]</sup>. In the study conducted by Hsu *et al*<sup>[12]</sup> to compare the joint position sense of the lower limb in patients with diabetic neuropathy and normal controls, they found that distal joint involvement precedes that of proximal joints. Also, Guney *et al*<sup>[13]</sup> found decrease in ankle joint position sense in diabetic patients, which was measured as the ability to reproduce target ankle dorsiflexion and plantarflexion actively. Owing to impaired proprioception, these individuals are at higher risk for fall-related injuries, which leads to high financial costs<sup>[13,14]</sup>.

Proprioception was defined as “the perception of joint and body movement as well as position of the body, or body segments, in space”<sup>[15]</sup>. In a study conducted by Park *et al*<sup>[16]</sup> to investigate the effectiveness of an ankle proprioceptive control program on gait of patients with chronic stroke, the study results provide evidence in support the effectiveness of ankle proprioceptive control program in improving gait ability of patients with chronic stroke. Also, Isakov and Mizrahi<sup>[9]</sup>, stated that, clinical training of proprioceptive sense is an important factor in treatment of patients with neurologic problems in order to increase gaiting ability.

Despite the strong relationship between ankle proprioception and gait ability which has been reported in the previous research studies, up till now, there is no study to assess to what extent ankle proprioceptive training can improve gait ability and decrease risk of falling in patient with diabetic neuropathy. So, the current study is the first randomized controlled study to investigate the effect of ankle proprioceptive training on gait and risk of falling in patients with diabetic neuropathy.

## PATIENTS AND METHODS

### Patients' selection

In this randomized controlled study, thirty patients diagnosed as type II diabetes were selected from the Out Patient Clinics of Neurology and Internal Medicine in Kasr Al- Aini Hospitals and Out Patient Clinic of Department of Neurology, Faculty of Physical Therapy, Cairo University in the period from March 2018 to January 2019.

Patients were eligible to participate in the study if they had peripheral neuropathy which has been previously diagnosed by a physician and confirmed by electrodiagnostic tests, age ranged from 50 and 65 years<sup>[17]</sup>, body mass index did not exceed 30 Kg/m<sup>2</sup>, type II diabetes mellitus diagnosed for at least 7 years<sup>[1]</sup>, able to walk without assistance or assistive device, able to stand on both feet and on one leg, and had controlled blood glucose level by the screening by Glycated Haemoglobin test (9 % > HbA1c > 6.5 %) <sup>[18]</sup>. While, patients were excluded from the study if they had cognitive deficits, severe retinopathy, scars under their feet, hypo or hypertension, any medical conditions that would confound assessment of neuropathy such as malignancy, active/untreated thyroid disease, other neurological or orthopaedic impairments (such as stroke, poliomyelitis, rheumatoid arthritis, or severe osteoarthritis), and severe nephropathy that causes edema or needs haemodialysis. A diagram of patients' retention and randomization throughout the study is shown in Figure 1. The figure shows that 43 patients were initially screened, after the screening

process 30 patients were eligible to participate in the study.

Patients were randomly allocated into an intervention group or a control group using sealed envelope with 15 patients in each group. Study group take ankle proprioceptive training plus traditional physical therapy exercises while control group take traditional physical therapy exercises only. During study period, both groups continued to receive the usual recommended medical care.

### Examination

All of the following assessments were done to all patients in both groups before and after 8 weeks of treatment program.

**Measurement of spatiotemporal gait parameters:** Spatiotemporal gait parameters including: (Walking velocity (cm/sec), step length of dominant limb (cm), step time (sec), cadence (step/min) and double support time (sec)) were measured using the Biodex Gait Trainer (Model 950-380, software version 2.6x, New York). The Biodex Gait Trainer is a special treadmill with an instrumented desk that designed to evaluate and train walking ability in patients with gait impairment<sup>[19]</sup>. For evaluations of gait parameters, each patient was first allowed to be familiar with gait trainer set up before starting recording the selected gait parameters. This was achieved through instructing the patient to walk over the gait trainer and to follow the tread belt movement for three to five minutes. This might be repeated two or three times till the patient became adapted and familiar with the apparatus. To start the evaluation process, the tread belt was ramped up slowly to 0.3 meter/hour. The speed setting was then increased gradually to a comfortable pace for each patient. Once the patient became comfortable, the data recording was started. Each patient was allowed to walk continuously for three minutes, then the evaluation session ended and the gait trainer slowed down gradually until it stopped and the results were displayed. These procedures were repeated three successive times with three minutes rest period in between trials. For each patient, gait parameters were averaged over the trials for further data analysis.

**Assessment of risk of falling:** Risk of falling was assessed with Fall Efficiency Scale- International (FES-I). This is a self-reported 16-item scale of perceived confidence to complete physical daily activities. It is administered to reflect the level of concern about falling in activities inside and outside the home. Each item is scored on a four-point scale (1 = not at all concerned, 2 = somewhat concerned, 3 = fairly concerned and 4 = very concerned). Possible total score is 64 in the worst case and 16 in the best condition to do

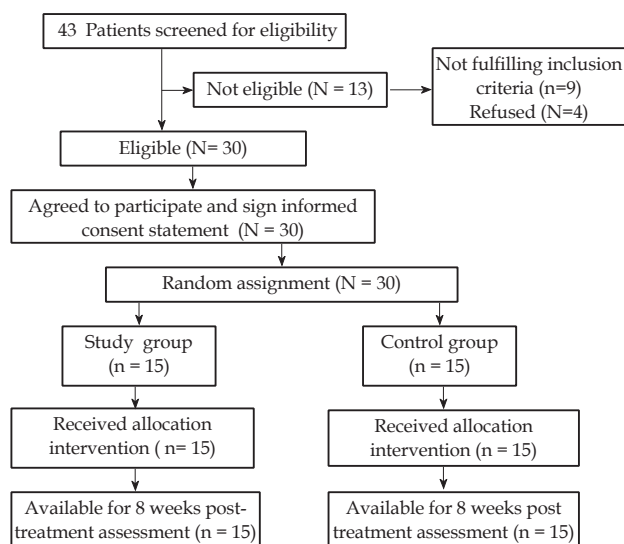


Figure 1 Flow diagram for randomized patient's assignment.

all tasks without any concern of falling<sup>[20]</sup>. Some studies have been supported validity of the FES-I questionnaire<sup>[21]</sup>.

**Intervention:** The same physiotherapist was responsible for all training sessions. In order to avoid bias, another physiotherapist performed all measurements. Patients in both groups received the same traditional physical therapy exercises for 8 weeks, three times a week, 30 min per session. The program included the following exercises as described by Richardson *et al*<sup>[22]</sup>: (1) Active range of motion exercises for ankle and subtalar joints were done for 5 min including: ( dorsiflexion, plantarflexion, eversion and inversion ) 10 repetition for each movement. (2) Functional balance training for 15 min involving: (A) Sit to stand ( 5 times). (B) Standing with shifting weight anteriorly, posteriorly, and sideway (5 times for each direction). (C) Functional reach sideway and anterior for touching targets set by the therapist (5 times for each direction). (D) Standing on heels for 20 seconds (5 times). (E) Standing on toes for 20 seconds (5 times). (3) Gait training for 10 min including: (A) Spot marching (2 min). (B) Walking over the heels, toes, lateral border of feet with the preferred speed (6 min). (C) Tandem walking in a straight line (2 min).

The study group additionally received ankle proprioceptive training, 3 times a week for 8 weeks, 30 min per session. Rest breaks were provided as needed, and the patients were instructed to tell the physiotherapist and stop the exercise immediately if they report any side effects such as fatigue or dizziness. The ankle proprioceptive training used in this study was implemented by correcting and supplementing the training programs used by Karakaya *et al*<sup>[23]</sup>, Lee *et al*<sup>[24]</sup> and Singh *et al*<sup>[25]</sup>, which included the following groups of exercises: (1) Training on the floor for 10 min (1-8 week): (A) Weight shifting on each direction (anteriorly, posteriorly and lateral side) combining with side to side head movements (5 times for each

direction). (B) One legged stance with slight knee flexion of other leg for 15 seconds (5 times for each leg). (C) One legged stance with increasing knee flexion of the other leg for 15 seconds (5 times for each leg). (2) Training on balance pad for 20 min (1-4 week): (A) Standing on a balance pad with shifting weight (anteriorly, posteriorly and lateral side) 10 times on each direction. (B) From standing position, bending and stretching both knees by squatting as much as possible (10 times ). (C) Standing with widening each feet forward and backward, then putting the body weight forward with bending and stretching knees (10 times ). (3) Training on rocked balance board for 20 min (5-8 week): (A) In standing position, moving the weight left and right maximally (5 min). (B) In standing position, moving the weight forward and backward maximally (5 min). (C) In standing position, moving both heels of feet up and down (5 min). (D) In standing position, bending and stretching both knees by squatting as much as possible (5 min).

**DATA ANALYSIS**

Statistical analysis was performed using statistical package for social studies (SPSS) version 22. Data were expressed as mean and standard deviation. Chi- squared test was used for comparison of sex distribution between groups. Mean changes within groups (pre and post) were analyzed using Paired t-test, while mean changes between groups were analyzed using unpaired t-test. The level of significance was set at  $p < 0.05$ .

**Subject characteristics:**

Table 1 showed the subject characteristics of both groups. There was no significant difference between both groups in the mean age, BMI, HbA1c, and duration of illness ( $p < 0.05$ ). Also, there was no significant difference in sex distribution between groups ( $p = 0.71$ ).

**Table 1** General characteristics of subjects in the study and control groups.

	Study group	Control group	t- value	p- value
Age (yrs)	57.6 ± 4.96	59.13 ± 4.2	-0.86	0.39*
BMI (kg/m <sup>2</sup> )	27.28 ± 1.6	26.68 ± 1.11	0.78	0.43*
HbA1c (%)	7.94 ± 0.52	7.71 ± 0.44	1.27	0.21*
Duration (yrs)	9.66 ± 3.01	10.8 ± 3	-1.55	0.12*
Males/Females	7/8	6/9	( $\chi^2 = 0.13$ )	0.71*

Data are expressed as mean ± SD;  $\chi^2$ :Chi squared value; \*  $p$  value > 0.05= non significant.

**Comparison of pre and post treatment for both study and control groups**

As shown in tables 2 and 3, there were significant differences between pre and post treatment in all measured variables in both study and control groups. As, step length, velocity and cadence showed significant increase post treatment compared with that pre treatment ( $p = 0.001$ ). Also, there was a significant decrease in FES-I, step time and double support time post treatment compared with that pre treatment ( $p = 0.001$ ).

**Table 2** Comparison between pre and post treatment mean values of each measured variable of the study group.

	Pre treatment	Post treatment	MD	% change	t-value	p-value
FES-I	36.26 ± 4.44	27.13 ± 4.53	9.13	25.17	24.27	0.001
Step length (cm)	51.66 ± 2.87	59.86 ± 3.04	-8.2	15.87	-16.11	0.001
Step time (sec)	0.62 ± 0.05	0.48 ± 0.08	0.14	22.58	11.91	0.001
Double support time (sec)	0.33 ± 0.04	0.25 ± 0.05	0.08	24.24	19.62	0.001
Velocity (cm/sec)	71.8 ± 6.8	80.06 ± 6.8	-8.26	11.5	-5.55	0.001
Cadence (step/min)	82 ± 2.92	98.06 ± 5.29	-16.06	19.58	-10.08	0.001

Data are expressed as mean ± SD; MD: mean difference;  $p$  value > 0.05: significant; Fall Efficiency Scale- International (FES-I).

**Table 3** Comparison between pre and post treatment mean values of each measured variable of the control group.

	Pre treatment	Post treatment	MD	% change	t-value	p-value
FES-I	34 ± 5.52	31.06 ± 4.93	2.94	8.64	9.29	0.001
Step length (cm)	52.06 ± 3.49	56.2 ± 3.21	-4.14	7.952	-12.29	0.001
Step time (sec)	0.63 ± 0.06	0.54 ± 0.07	0.09	14.28	5.49	0.001
Double support time (sec)	0.32 ± 0.03	0.29 ± 0.04	0.03	9.37	4.1	0.001
Velocity (cm/sec)	70.93 ± 8.06	74.13 ± 7.9	-3.2	4.51	-13.16	0.001
Cadence (step/min)	80 ± 5.65	88.06 ± 4.7	-8.06	10.07	-10.63	0.001

Data are expressed as mean ± SD; MD: mean difference;  $p$  value > 0.05: significant; Fall Efficiency Scale- International (FES-I).

### Comparison of pre and post treatment between study and control groups

As shown in table 4, there was no significant difference between the study and control groups in all measured variables pre-treatment ( $p > 0.05$ ). While, post treatment there was a significant increase in step length, velocity and cadence of the study group compared with that of control group ( $p > 0.01$ ). Also, there was a significant decrease in FES-I, step time and double support time of the study group compared with that of control group ( $p = 0.001$ ).

## DISCUSSION

Patients with DPN often exhibit greater impairments in posture and gait and are typically at increased risk of falling<sup>[26]</sup>. These impairments in balance and gait result from a range of deficits, including proprioception and muscle strength<sup>[13,27]</sup>. So, this study was conducted to determine the effect of ankle proprioceptive training on gait and risk of fall in patients with diabetic neuropathy.

The results of the current study showed that, the study group who received ankle proprioceptive training in addition to traditional physical therapy exercises has a significant improvement in spatiotemporal parameters (walking velocity, step length of dominant limb, step time, cadence, and double support time) and a significant reduction in the risk of falling than the control group who received traditional physical therapy exercises only. This results comes in agreement with the findings of Martínez-Amat *et al*<sup>[28]</sup> who mentioned that, 12 weeks proprioception training program in older adults is effective for improving gait, and decreasing the risk of falling in adults aged 65 years and older.

The results of the current study regarding the significant improvement of the gait parameters in the study group than the control group, might be explained by several mechanisms. This is because, walking is a highly integrated function that requires the coordinated contribution of multiple physiological subsystems<sup>[29]</sup>. The first explanation is related to the role of proprioceptive training in improving muscle activity around the ankle joint<sup>[30]</sup>, which consider as a key factor influencing gait abnormalities in people with DPN. This explanation was supported by Park *et al*<sup>[16]</sup> who mentioned that ankle proprioceptive control program leads to significant improvements in ankle dorsiflexors strength and gait of patients with stroke.

The ability to maintain balance in standing position is a fundamental factor of stable independent gait and sensitively affects gait velocity<sup>[31,32]</sup>. Thus, the second explanation for the significant improvement of spatiotemporal gait parameter in the study group than the control group might be attributed to the role of proprioceptive training in improving balance, which lead to improvement in gait ability<sup>[33]</sup>. This explanation was supported by Han *et al*<sup>[34]</sup> who stated that, ankle proprioception training plays an essential role in balance control. Also, El-wishy and ElSayed<sup>[35]</sup>, concluded that, proprioceptive training was effective in improving functional balance and reducing balance indices in patients with diabetic neuropathy.

During proprioceptive training, the gradual progression to more unstable balance board could be used as a method to increase the level of difficulty. Training on unstable surfaces help in improving muscle activity around the ankle joint, and reducing the time to contract the calf muscle than stable surfaces<sup>[36]</sup>. So, the third explanation regarding the results of spatio-temporal parameters of gait, could be attributed to use of balance pad and balance board during the proprioceptive training. This explanation supported by Osborne *et al*<sup>[37]</sup> who conducted a study to investigate the effects of ankle disk training on muscle reaction time in subjects with a history of ankle sprain, and the results revealed a statistically significant

**Table 4** Comparison between study and control groups on each measured variable before and after treatment.

	Study group	Control group	MD	t-value	p-value
<b>Pre treatment</b>					
FES-1	36.26 ± 4.44	34 ± 5.52	2.26	1.23	0.22*
Step length (cm)	51.66 ± 2.87	52.06 ± 3.49	-0.4	-0.34	0.73*
Step time (sec)	0.62 ± 0.05	0.63 ± 0.06	-0.01	-0.06	0.95*
Double support time (sec)	0.33 ± 0.04	0.32 ± 0.03	0.01	0.65	0.501*
Velocity (cm/sec)	71.8 ± 6.8	70.93 ± 8.06	0.87	0.31	0.75*
Cadence (step/min)	82 ± 2.92	80 ± 5.65	2	1.21	0.23*
<b>Post treatment</b>					
FES-1	27.13 ± 4.53	31.06 ± 4.93	-3.93	-2.27	0.03**
Step length (cm)	59.86 ± 3.04	56.2 ± 3.21	3.66	3.2	0.003**
Step time (sec)	0.48 ± 0.08	0.54 ± 0.07	-0.06	-2.32	0.02**
Double support time (sec)	0.25 ± 0.05	0.29 ± 0.04	-0.04	-2.16	0.03**
Velocity (cm/sec)	80.06 ± 6.8	74.13 ± 7.9	5.93	2.2	0.03**
Cadence (step/min)	98.06 ± 5.29	88.06 ± 4.7	10	5.47	0.001**

Data are expressed as mean ± SD; MD: mean difference; \*  $p$  value > 0.05= non significant; \*\*  $p$  value < 0.05: significant; Fall Efficiency Scale-International (FES-I).

decrease in the onset latency of anterior tibialis muscle after ankle disk training. Also, Clark and Burden<sup>[38]</sup> reported that, after 4-week wobble board training, there was a significant decrease in muscle onset latency and a significant improvement in perceived stability in individuals with a functionally unstable ankle.

In addition, training on a soft, unstable surface in the proprioceptive group is more likely to increase the plantar cutaneous sensation and joint position sensation, which are considered as an important factors in standing balance and ambulation<sup>[39,40]</sup>. This explanation was confirmed by Shumway-Cook and Wool lacott<sup>[41]</sup>, who reported that, unstable surfaces were effective for improving foot proprioception. Also, McIlroy *et al*<sup>[40]</sup> reported that increased postural sway on an unstable surface resulted in increasing the postural reflex activity which characterized by increased afferent input from the cutaneous receptors in the soles of the feet.

Regarding the risk of fall, although both groups produced statistically significant reduction in the risk of fall at post-exercise compared with pre-exercise, statistically significant reduction was detected in the ankle proprioceptive group compared with the traditional exercises group. These findings might be attributed to the reported significant improvement of walking in the study group than the control group. This explanation was supported by Allet *et al*<sup>[8]</sup> who mentioned that, difficulties in walking in patients with diabetic neuropathy results in higher risk of falling and injuries. Also, Cavanagh *et al*<sup>[42]</sup> suggested that, fall in patients with DPN most commonly occur during gait.

Repeated falls lead to increase the person's fear of falling even more, which is accompanied by a loss of confidence or self-efficacy in one's ability to perform routine activities associated with daily life<sup>[43]</sup>. Several researchers stated that, promoting physical functioning lead to increased confidence and a reduced fear of falling<sup>[44,45]</sup>. In the current study, most of the patients in the study group reported a reduced fear of falling as the training program progressed, and patients stated that, they moved with greater ease and more confidence after their participation in the intervention program. Therefore, it was the psychological effects that led to the significant reduction in risk of fall in the study group than the control group.

It is necessary to note the limitations of this study. First, the sample size was small, which potentially limits the generalizability of these



findings. In addition, the study considered only the immediate effects of ankle proprioceptive training on gait and risk of fall in patient with diabetic neuropathy, and did not reflect the long term effects. Furthermore, it was not possible to blind the physiotherapist due to the nature of the interventions which need the direct communication between the physiotherapist and the patients.

## CONCLUSION

The results of the present study showed that, the addition of ankle proprioceptive training to traditional physical therapy exercises could provide more improvement of gait ability and decreasing risk of falling in patient with diabetic neuropathy.

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