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Differences in the level of functional ability between diabetic peripheral neuropathy patients both with and without functional limitations

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KEYWORDS

Diabetic mellitus; Diabetic peripheral neuropathy; Physical function; Functional limitation.

ABSTRACT

Diabetic Peripheral Neuropathy (DPN) is an important complication of diabetic mellitus. The primary symptom of DPN disrupts the integration of the somatosensory system contributing to both static and dynamic balance ability. Furthermore, muscles progressively decline in distal to proximal parts of the body. The combination of muscle weakness and balance impairment obviously leads to gait abnormality, then it is directly linked to functional limitations. The study aimed to compare the functional ability, both with and without functional limitations, in type 2-diabetes mellitus (T2DM) with diabetic peripheral neuropathy (DPN). This study was cross- sectionally collected the data in DPN patients from 25 sub-district health promoting hospital, Nakhon Phanom Province in the Northeastern of Thailand. They were diagnosed as DPN using the Michigan Neuropathy Screening Instrument (MNSI). Then, they were screened for functional limitation using the late-life function and disability instrument (Late-life FDI) questionnaire. The eligible participants were assessed by hand grip dynamometer (HGD), toe grip dynamometer (TGD), five times sit-to-stand test (FTSST), single leg stance test (SLS), timed up and go test (TUG), and 10-meter walk test (10MWT). Sixty-four eligible subjects were divided into two groups: a non- functional limitations group (45 subjects) and a functional limitations group (19 subjects). According to the findings, approximately 30% of the DPN patients were reported with functional limitations. The DPN patients with functional limitations were reported with significantly poorer muscle strength (hand grip and toe grip strength, and leg muscle strength), static and dynamic balance ability, and gait speed than the other group (p-value < 0. 05). The present study suggested the level of functional ability in these individuals could be meaningful for health practitioners in preventing severe complications and disability from functional limitation conditions.

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Introduction

Diabetic peripheral neuropathy (DPN) is one of the most significant complications of diabetes mellitus (DM)[1]. DPN occurs due to the progressive diffuse or focal degeneration of peripheral somatic and autonomic nerve fibers[1]. The chronic hyperglycemia of diabetes is related to long-term damage, dysfunction, and the failure of various organs[2]. Evidence reports a high prevalence of DPN in South East Asia[3], in which there was an estimated 34% prevalence of DPN patients in Thailand[4].

DPN invariably leads to several serious health problems. The primary symptom of DPN is abnormal sensation in the toes; then, it may extend to involve the feet and legs in a stocking distribution[5]. Consequently, DPN induces the risk of foot ulcers, which are the result of abnormal weight bearing on the feet due to the loss of sensation[6]. Motor and sensory neuropathy also results in abnormal foot muscle mechanics and developed structural changes in the foot, gangrene, and finally amputation[6]. These impairments disrupt the integration of the somatosensory system contributing to both static and dynamic balance ability. Particularly in severe or longer duration DPN, motor fibers are involved, and then motor functions (i.e., atrophy and weakness) are progressively decline in distal to proximal parts of the body[7]. The combination of muscle weakness and balance impairment obviously leads to gait abnormality[8]. The negative impacts of DPN influence the ability to perform daily activities such as bathing, shopping, and doing housework. The evidence confirms that DPN is directly linked to functional limitations, which impacts the quality of life in these individuals[7-9].

Although some of the previous studies investigated physical performance between DPN and non-DPN patients[10-12], they reported on some aspects of functional ability in these patients. Furthermore, none of the studies reported on functional ability in DPN both with and without functional limitations. Early detection of the functional limitations of DPN patients based on their significant impairments including distal muscle (hand grip and toe grip strength) and leg muscle strength, static and dynamic balance ability, and gait speed, is crucial in preventing severe consequences from the functional limitations in these individuals. These abilities can be quantified using the hand grip dynamometer (HGD), toe grip dynamometer (TGD), five times sit-to-stand test (FTSST), single leg stance test (SLS), timed up and go test (TUG), and 10- meter walk test (10MWT), respectively[13,14] . These functional tests are commonly used because their methods are simple, inexpensive, and easy to perform; they provide quantitative data and report an acceptable level of reliability in DM patients[15]. The information regarding the physical abilities of these patients assists both physical therapists and health practitioners in preventing severe complications and disability from functional limitation conditions. Therefore, this study aimed to compare functional abilities in terms of hand grip strength, toe grip strength, leg muscle strength, static and dynamic balance ability, and gait speed between DPN patients both with and without functional limitations.

Materials and methods

Study design and population

The study was a cross-sectional data collection of the functional ability in DPN patients both with and without functional limitations. The number of sample size was calculated based on a pilot study (20 persons of both two groups) for detecting a difference between the means of two samples. In calculating the sample size, the α error and β error were set as 0.05 and 0.2, respectively. There were six parameters (HGD, TGD, FTSST, SLS, TUG, and 10MWT) in the study; therefore, the variance was ranged between 0. 28 to 11. 92, and the effect size was ranged from 0. 58 to 14. 89. Thus, the largest number of subject of all parameters was 19 persons/group. The subjects were male and female type 2-diabetes mellitus (T2DM) with DPN. They were from an out-patient diabetic clinic of 25 sub-district health promoting hospitals that are a network of Nakhon Phanom Hospital in the Northeastern Thailand.

The subjects had been diagnosed by a doctor as T2DM for at least 10 years. Their DPN was subsequently determined using the criteria of the Michigan Neuropathy Screening Instrument

(MNSI). The MNSI consisted of two separate parts: DPN was defined if they had a score of at least 7 out of 13 on the first part (self-administered questionnaire), and a score of at least 2.5 out of 10 on the second part (physical assessment)[16, 17]. To complete the protocol of the study, it was important that the subjects were able to understand simple commands. However, they were excluded if they had any abnormalities that might affect the study, including the following: (1) neurological diseases (e.g., cerebrovascular disease and Parkinson's disease) in which their impairments still interfered gait and balance ability, (2) open wounds on the weight-bearing surface of the foot, any deformities (foot or hand), or amputations that might affect the protocol, (3) inflammation of joints and muscles, or any musculoskeletal conditions such as osteoarthritis or gouty arthritis with a pain score of more than 5 out of 10 on a visual analogue scale, or any pain that affected the study, (4) a history of ankle, knee or hip joints replacement at least 6 months prior to participating in the study, or any residual effects in performing the test, (5) the use of drugs that had negative potential effects on cognition, alertness, and psychomotor function (e.g., opioids, antiepileptics, anxiolytics, antipsychotics, hypnotics, or sedatives), and (6) any signs or symptoms that might influence the study such as dizziness, visual and auditory impairments, angina pain, uncontrolled hypertension, and acute illness or injury. The protocol of the study was approved by Khon Kaen University Ethics Committee for Human Research (HE622004). Eligible individuals were required to sign a written informed consent prior to participation in the study.

Study protocol

The eligible subjects were screened for their demographic characteristics and health status, including the information regarding DM (i. e. , the duration of DM, the presence of symptoms, and the glucose level) using screening questionnaire. They also were interviewed functional limitations using the Late- life Function and Disability Instrument (Late- life FDI). This tool evaluates both the frequency of performing life- tasks and the limitations in capability to perform life-task. The functional components of the Late-life FDI include 7 items of the upper extremity and 25 items of the lower extremity. The dimensions of the upper extremity function include removing wrapping with the hands only and holding a full glass of water in one hand. The lower extremity functions consist of walking around one floor at home, picking up a kitchen chair, carrying while climbing stairs, and walking on a slippery surface[18]. The function component has a rating scale from 1 to 5; a score of 1 is defined when the subject feels completely limited in performing a particular task; whereas, a score of 5 is described as not at all limited in doing the activity. The total score of the function component was 160, which was calculated based on the summary scores of 32 items. The raters had to transform the raw data into the scaled scores (0-100). Scores of less than 53.2 out of 100 are considered a determined functional limitation[19]. Then, the eligible subjects were appointed to perform the functional tests.

The subjects were assessed for their muscle strength using the HGD, TGD, and FTSST. Their static and dynamic balance ability was examined using the SLS and TUG, respectively. Their gait speed was measured using the 10MWT. The details of the tests were explained as below:

HGD: The HGD was used to assess hand grip strength (HGS), which is the maximum power of the forceful flexion of all fingers. This test was reported high test-retest reliability (ICC = 0.95) in older adults. The subjects were asked to sit straight in a chair, without an armrest and with their arms hanging loosely at their sides. Their shoulder (on the dominant hand) was slightly abducted, at 15 degrees with elbow extension, the forearm in the neutral position, and the wrist with slight extension. They were instructed to squeeze the handle as hard as possible using the dominant hand and then hold for 3 seconds[20]. A 30-second rest was given between each of 3 trials and the average weight was recorded in kilograms.

TGD: The TGD represents toe grip strength (TGS), which is a complex motion involving several muscles in the foot, including the flexor hallucis brevis, flexor hallucis longus and lumbricals

muscles[21]. Toe grip strength was measured using the footedness test on the dominant foot, which is defined as the one with the toe used to kick a ball. The subjects were instructed to sit straight in an armless chair with their arms crossed over their chest, flexing their hip and knee joints at 90 degrees, and keeping their ankle joints in the neutral position. The first proximal phalanx of the foot was positioned on a grip bar and the heel position was fixed using a heel stopper and immobilization belt. Then, they were asked to grip the bar with maximum force and hold for 3 seconds. The test was measured in 3 trails with 30-second intervals, and the average value was recorded in kilograms.

FTSST: The FTSST was used to represent the strength of lower extremities. The subjects were asked to sit on an armless chair with a seat height of 43 cm. Then, their hips were flexed at 90 degrees, the ankle joints were kept 10 cm behind the knees, and their back touched the backrest. They were instructed to keep their arms crossed over their chest. Then, the time was recorded using a stopwatch. After the command "go", the subjects had to stand up and sit down 5 times continuously as quickly as possible and safe. The time was stopped when they completed 5 chair rise cycles with their back touching the backrest. The subjects were asked to perform 3 trials and the average time was recorded in seconds[14].

SLS: The SLS test is one of the most challenging tasks for the DPN patients, which evaluates the static balance by reducing base of support[9]. The subjects were instructed to choose the leg side that they preferred for the test. They were permitted to use the other leg if they had pain in the preferred leg. Then, they were instructed to keep their leg from touching and try to stand on one foot for as long as possible with their arms beside their trunk and their eyes open[11]. The time was started after the command "begin", and stopped when the subjects stepped out of position, lost balance control, or reached the 60-second time limit[11]. The average time for their ability to maintain the stances was calculated in seconds from 3 trials.

TUG: The TUG test is widely used to assess balance ability while changing position from sitting to standing, walking, and turning. The subjects were instructed to sit on an armless chair with a seat height of 43 cm. The starting position was set with their hips flexed at 90 degrees, ankle joints kept 10 cm behind the knees, and back touching the backrest[22]. Then, they were asked to keep their arms beside their body. After the command "go", they had to stand up from the chair without using their arms, walk around a traffic cone that was placed 3 meters from the chair, and return to sit down on the chair at the maximum and safe speed. The time was recorded after the "go" command and it was stopped when their back touched the backrest of the chair. The average time from 3 trials was calculated in seconds[22].

10MWT: The 10MWT is used to quantify gait speed; this measure represents health outcomes, including hospitalization, falls, disability, and mortality. Subjects were asked to walk with a comfortable pace and safe speed along a 10-meter walkway. They started walking after the command "go". Then, the time was recorded in the middle 4 meters using a stopwatch. The time was recorded when the participant's greater trochanter passed the marked tape on the floor at the first 3 meters. After that, the time was stopped when the same side of the greater trochanter passed at 7 meters. The subjects performed 3 trials and the average time was converted to gait speed in meters/second[23].

The subjects were able to rest as needed between the trials, for their vital signs (blood pressure, heart rate, and respiratory rate) to return to normal, which were monitored using the digital blood pressure monitoring. They could stop performing the tests if they had any abnormal signs or symptoms such as aggravated pain, acute illness, or injury. For safety and to prevent falls, the researchers stood or walked beside the subjects during the test, without interrupting their movement. In addition, the subjects were asked to wear sandal shoes and a safety belt that was prepared by the researchers. The sequence of the tests was random to minimize learning and fatigue effect. There were two raters

in the study: both were a physical therapist; they clarified their ability to use the tests by practicing a standard protocol compiled by an expert. The intra- and inter-rater reliability of all of the functional tests were reported at an excellent level in which the intraclass correlation coefficients (ICC) ranged between 0.856 and 1.00; *p*-value < 0.05.

Statistical analysis

The SPSS for Windows was used to analyze the collected data (SPSS Statistic version 17.0, IBM Corporation, 1 New Orchard Road Armonk, New York 10504-1722, USA, serial number: 5068054). Descriptive statistics were utilized to describe the demographic characteristics of the subjects in terms of mean, standard deviation, and percentage. The differences in the demographic characteristics and the functional abilities between the groups were compared using the chi-square test for the categorical variable and the independent t-test for the continuous variable. A *p*-value was set at less than 0.05.

Results

A total of 661 DM patients agreed to participate in the study; however, 597 of them were excluded due to many reasons as shown in Figure 1. Therefore, 64 DM patients with DPN were involved in the study; all of them were interested and willing to participate the study. Therefore, they were divided into two groups: a non-functional limitation group (45 subjects) and a functional limitation group (19 subjects). There were 4 subjects in non-functional limitation group and 14 subjects in functional limitation group, who were unable to complete the FTSST and SLS due to aggravated pain and fear of fall during standing on one leg. Of the DPN patients, 30% reported functional limitations (MNSI score of 12.42 ± 1.73 scores). More than half of the subjects were female (73.44%). They also reported other underlying diseases, such as hypertension, dyslipidemia, and renal diseases. The average duration of DM was 15.30 ± 5.39 years for all of the subjects. In the last 6 months, 26.56% had experienced a fall; the number of falls ranged between 1 and 2. Around 21% of the functional limitations group reported using a gait device, including walker frame and tripod cane. Other demographic characteristics are shown in Table 1.

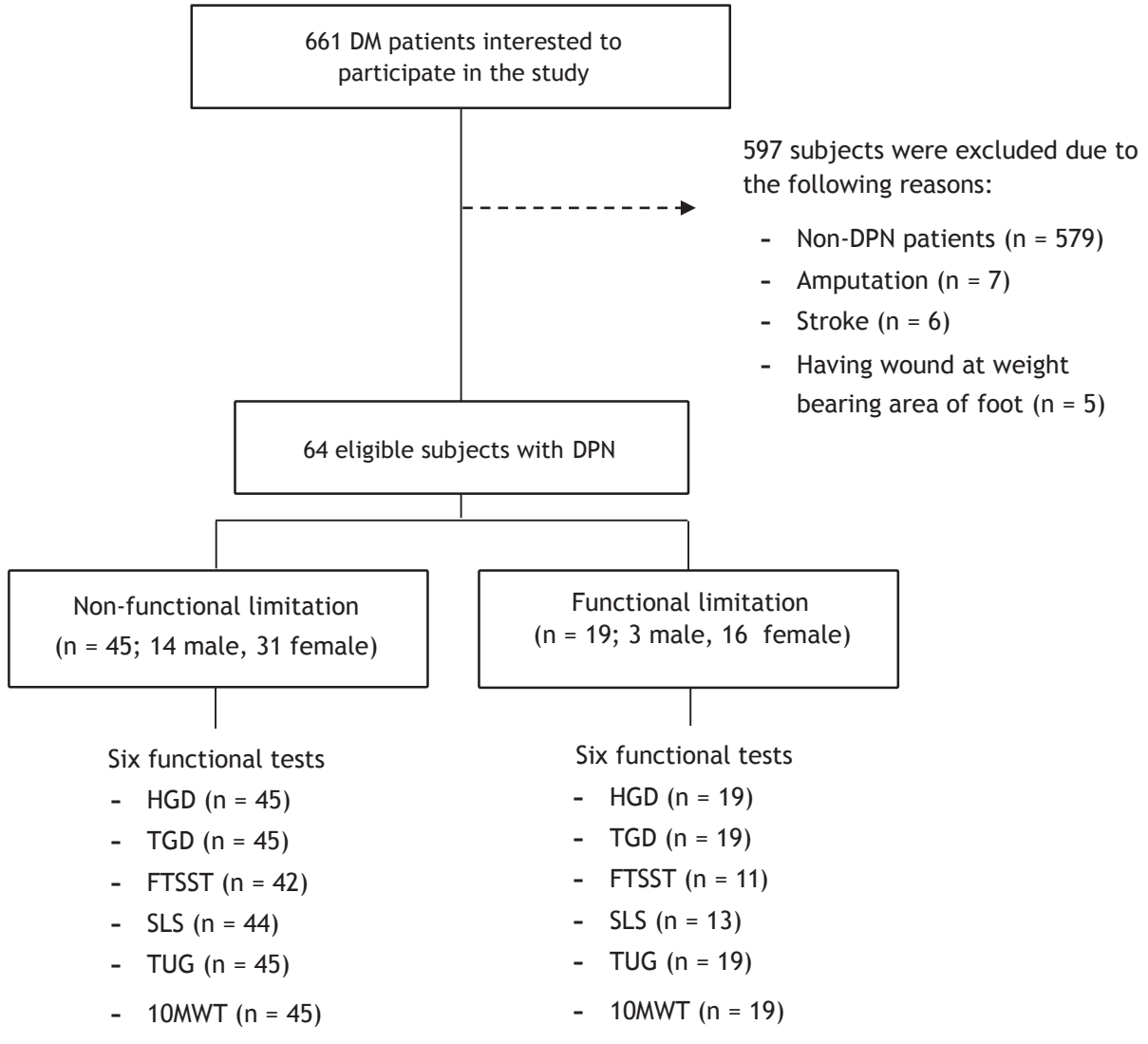

Figure 1 Subjects participation flow chart

Table 1 Demographic characteristics of the diabetic peripheral neuropathy patients with and without functional limitation (n = 64)

Variable	Non-functional limitation (n = 45)	Functional limitation (n = 19)	p-value
	Mean ± SD (95% CI)	Mean ± SD (95% CI)	
Gender: Female (n, %) [a]	31 (68.89)	16 (84.21)	0.205
Age (years) [b]	65.09 ± 9.81 (62.14 – 68.04)	68.11 ± 6.97 (64.75 – 71.46)	0.229
Weight (kg) [b]	61.47 ± 10.35 (58.36 – 64.57)	53.34 ± 11.81 (47.65 – 59.04)	0.008*
Height (cm) [b]	158.27 ± 8.48 (155.71 – 60.81)	152.94 ± 6.36 (149.88 – 156.01)	0.017*
BMI (kg/m^2) [b]	24.45 ± 3.05 (23.53 – 25.36)	22.62 ± 3.74 (20.82 – 24.42)	0.044*
Duration of DM (years) [b]	14.87 ± 5.19 (13.31 – 16.43)	16.32 ± 5.86 (13.49 – 19.14)	0.329
Underlying disease, except DM (numbers) [b]	1.18 ± 0.98 (0.88 – 1.47)	1.26 ± 0.81 (0.87 – 1.65)	0.739
Walking aid (n, %) [a]			
Do not use	45 (100)	15 (78.95)	0.001*
Use	0 (0)	4 (21.05)	
History of fall (n, %) [a]			
No	35 (77.78)	12 (63.16)	0.226
Yes	10 (22.22)	7 (36.84)	
MNSI (scores) [b]			
Total scores	11.80 ± 1.53 (11.34 – 12.26)	12.42 ± 1.73 (11.59 – 13.26)	0.159
Subjective part	7.22 ± 0.64 (7.03 – 7.41)	7.42 ± 0.96 (6.96 – 7.88)	0.333
Objective part	4.58 ± 1.36 (4.16 – 4.98)	5.00 ± 1.17 (4.44 – 5.56)	0.242

Note:
[a] Data are presented using the number of subjects (percentage of total subjects).
[b] Data are presented using the mean ± standard deviation (95% confidence intervals).
* indicates significant difference (p-value < 0.05).

The differences in the functional ability (measured using the HGD, TGD, FTSST, SLS, TUG, and 10MWT) between the groups are shown in Table 2. The findings showed a statistically significant difference in all of the functional abilities between the DPN patients, both with and without functional limitations (p-value < 0.001).

Table 2 Functional ability between the diabetic peripheral neuropathy patients who with and without functional limitation (n = 64)

Variable	Non-functional limitation (n = 45)	Functional limitation (n = 19)	*p-value*
HGD (kg)	21.61 ± 7.64 (19.32 – 23.91)	15.28 ± 6.37 (12.21 – 18.35)	0.002*
TGD (kg)	6.13 ± 4.23 (4.86 – 7.39)	2.79 ± 2.49 (1.59 – 3.99)	0.002*
FTSST (sec)	13.70 ± 4.25 (12.38 – 15.03)	21.28 ± 7.41 (16.30 – 26.26)	< 0.001*
SLS (sec)	11.15 ± 9.45 (8.28 – 14.02)	3.14 ± 2.12 (1.86 – 4.43)	0.004*
TUG (sec)	12.13 ± 2.94 (11.24 – 13.01)	24.52 ± 9.38 (20.00 – 29.05)	< 0.001*
10MWT (m/s)	0.93 ± 0.19 (0.88 – 0.99)	0.53 ± 0.21 (0.43 – 0.63)	< 0.001*

Note:
Data are presented using the mean ± standard deviation (95% confidence intervals).
* indicates significant difference (*p*-value < 0.05).

Abbreviations:
HGD = hand grip dynamometer; TGD = toe grip dynamometer; FTSST = five times sit-to-stand test; SLS = single leg stand test; TUG = timed up and go test; 10MWT = 10-meter walk test.

Discussion

This study informed the differences in functional ability in the DPN patients both with and without functional limitations. Functional ability was investigated in terms of hand grip strength, toe grip strength, leg muscle strength, static and dynamic balance, and gait speed using the HGD, TGD, FTSST, SLS, TUG, and 10MWT, respectively. Approximately 30% of the DPN patients reported functional limitations. The findings showed a statistically significant difference in all of the above functional abilities between the groups (*p*-value < 0.05, Table 2).

The evidence indicated that approximately 30 to 50% of the patients with DM developed DPN. Interestingly, the present study found that around 30% of the DPN patients progressed to functional limitations. The findings additionally confirmed a loss of muscle strength of the intrinsic muscles of hand and foot, and of the leg muscles in DPN patients with functional limitations using the HGD, TGD, and FTSST (15.28 ± 6.37 kg, 2.79 ± 2.49 kg, and 21.28 ± 7.41 sec; respectively; *p*-value = 0.002 and < 0.001, Table 2). A previous study reported hand grip strength in male and female DPN patients (27.0 ± 9.4 and 21 ± 4.1 kg, respectively)[24], although the present findings were not separated by gender, the values were close the DPN patients with non-functional limitations (21.61 ± 7.64 kg). Furthermore, the hand grip strength in the DPN patients with functional limitations was significantly less than that in those with non-functional limitations, eventually manifesting in toe grip strength which are the intrinsic muscle as well, which are the intrinsic muscles (Table 2). Patients with loss of

toe grip strength should be suggested to wear the appropriate shoes to reduce diabetic foot ulcers and prevent falls. DPN patients have a decrease in muscle strength, while more severe degrees of DPN further exacerbate this decline. Although the present study did not divide the patients by severity of DPN, the average duration of DM in the present study was reported as 15.30 ± 5.39 years, which was longer than that in the previous studies[25]. However, both for clearer findings and to lead to a proper intervention plan, further investigation should concern the severity of the DPN.

When focusing on leg muscle strength, the present study applied the FTSST because it is commonly used in clinical and community settings with a high correlation to knee extension force and leg press force. However, some subjects were unable to complete the task due to aggravated pain (Figure 1) and the researchers asked them to rest and stop the test. Although there were no severe injuries, attentiveness should be a concern in future investigation. The findings reported that the subjects with functional limitations took a significantly longer time to perform the test than those with non-functional limitations (21.28 ± 7.41 sec and 13.70 ± 4.25 sec, respectively; *p*-value < 0.001, Table 2). Previously, there were no any studies reporting the FTSST for describing leg muscle strength in DPN patients. Goldberg and colleagues reported the cut-off score of the FTSST as 14.2 seconds for discriminating the fall risk in the elderly[26]. Therefore, the DPN patients with functional limitations might take a risk of fall, as they reported their fall experience as 36.84% in the past 6 months. The evidence shows that deficits in lower limb muscles reduce functional capacity and contribute to impaired balance and gait in DPN patients.

The present study investigated both static and dynamic balance in these DPN patients, using the SLS and TUG. The subjects with functional limitations were able to stand on one leg for a very short duration (3.14 ± 2.12 sec) in comparison to the non-functional limitations group (11.15 ± 9.45 sec) (Table 2). Similarly, Bohannon and colleagues reported the average time of SLS in the elderly with functional limitations as 3.2 ± 3.3 seconds[27]. The possible reasons might occur due to the similar characteristics of the subjects after considering the age range and gender. A previous study reported a cut-off score of the SLS as 30 seconds to indicate a decrease in accurate proprioceptive information from the lower extremities, which resulted in postural instability in the DPN patients[13]. Therefore, all of the subjects in the present study were a frailty group who had the impairment of balance ability. Although evidence supported that SLS is easy to perform with high sensitivity[27], they still reported fear of falling when performing the SLS test. Therefore, the application of this test in the DPN patients should take their fear of falling while standing on one leg into consideration.

In the measurement of dynamic balance using the TUG, the DPN patients with functional limitations were reported with twofold poorer balance ability than the other group (24.52 ± 9.38 sec and 12.13 ± 2.94 sec; *p*-value < 0.001). Another previous study reported that a time greater than 13.5 seconds to complete the TUG determined risk of fall in the DPN patients[12]; this value is lower than that of those with functional limitations in the present study. This might have occurred due to the difference in the DM duration, which was longer in the present than the previous study. Further instability of postural control is caused by the destruction of the somatosensory, visual, and vestibular systems by the pathologic condition of DPN[28]. Moreover, the complications of DPN were not only caused by motor dysfunction but also by impaired sensory function, which increased the risk of falls due to the loss of static and dynamic balance. Consequently, it might be a reason for the fall in these patients. While the present study reported the incidence of fall as 22.22%, the rate might increase to 36.84% in DPN with functional limitations (Table 1). Evidence has shown that focusing on muscle strength and balance ability is an effective method of determining the degree of autonomy in walking in these patients[29].

The present study also investigated gait speed in DPN patients; these findings showed a statistically significant difference between the functional and non-functional limitation groups

(0.53 ± 0.21 m/s and 0.93 ± 0.19 m/s, respectively; *p*-value < 0.001). A previous study reported that a gait speed of less than 0.8 m/s indicated a high risk of frailty and disability in the elderly[30]. A poor gait speed in a DPN patient with functional limitations might relate to a loss of plantar cutaneous sensation, which induced a slow gait speed in these patients. DPN patients are always reported as having an incorrect pressure distribution on the foot, increased time in the stance phase, and shorter steps, which also reveal a slow gait speed. Prolonged DPN results in a significant loss of muscle strength, which contributes to balance impairment and altered gait speed.

Nevertheless, there were some limitations of the study. First, the subjects were not analyzed separately as male and female. For clearer findings and to verify the effect of gender on the level of functional ability in these individuals, further study should analyze the data by gender. Second, the present study did not divide the patients by severity of DPN. The results in the early stage of DPN include a deficit of sensory, which may lead to a major dysfunction of the neuromuscular system. However, in the severe stage, the combination of sensory deficits and motor dysfunction may occur and contribute to decreased functional capacity, impaired mobility, altered gait, and increased fall risk[7]. Further study should consider an assessment that indicates the severity of the DPN. This finding might help health practitioners in detecting an early degree of DPN for proper management.

Conclusion

The present findings suggested the level of functional ability in DPN patients; individuals with functional limitations were reported with significantly poorer functional ability (in terms of muscle strength, balance ability, and gait speed) than those with non-functional limitations. These abilities might affect the capability to perform the activities in daily living independently; therefore, knowledge of the functional ability level could be beneficial for health practitioners in preventing any severe complications from functional limitations in the DPN patients.

Take home messages

Approximately 30% of DPN patients were reported functional limitations with significant poor muscle strength, balance ability, and gait speed. These deteriorations induced risk of fall in these individuals; therefore, physical therapists and health practitioners could suitably plan to prevent further complications from functional limitations in DPN patients.

Conflicts of interest

The authors declare no conflict of interest.

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