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Effect of Cognitive dual-task Training on Postural Stability in older Adults with Diabetic Peripheral Neuropathy: A Randomized Control Trial

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Abstract

Aims: Accelerated cognitive decline in older adults with type 2 diabetes mellitus is associated with poor performance in postural balance. Also, diabetic peripheral neuropathy may lead to increase postural sway and muscle weakness in lower extremities. This study investigate the effectiveness of sensory-motor program combined with cognitive dual-task training on postural stability in elderly with diabetic peripheral neuropathy. Methods: A total of 40 patients diagnosed with diabetic peripheral sensory motor neuropathy with average age from 55–70 years were involved in this study. The patients were randomly divided into two equal groups. Group 1 (the control group) received a sensory-motor exercise program for diabetic peripheral neuropathy patients. Group 2 received cognitive dual-task training in addition to the same selected physical therapy program for Group 1. Patients were assessed for posture stability before and after treatment using the Biodex Balance System. The intervention took place three times a week for 8 weeks. Results: There was significant improvement of postural stability in both Groups with experimental Group showing the most improvement. Limit of stability revealed significant improvement, only in experimental group. Conclusion: Cognitive dual-task training in combination and sensory-motor exercises are effective interventions for improving postural stability in patients with diabetic peripheral neuropathy, and the combination of the two interventions increases postural stability and limit of stability.

Key words: Diabetic Peripheral neuropathy, cognition, dual-task, postural stability, biodex balance system.

Introduction

Diabetes mellitus (DM) is swiftly emerging health problem in developing countries. Due to its chronic nature, it causes many debilitating complications including neuropathy, retinopathy, and nephropathy and macro vascular disease. (Jember *et al.*, 2017) Diabetic peripheral neuropathy (DPN) is one of the most long-term comorbidities of diabetes mellitus type 2. (Brown *et al.*, 2016) It involves damage to the nerve fibers or entire nerve cells. Some DPN patients may have extremely painful symptoms, others may be asymptomatic. (Jember *et al.*, 2017; Gholami *et al.*, 2018) Sensory and motor nerve damages in lower extremities due to DPN, may lead to the lack of accurate proprioceptive information –specially in the ankle joints-, (Ghanavati *et al.*, 2012) increased reaction time with slower response to postural shift, increased postural sway in static standing (Jernigan *et al.*, 2012; Gu and Dennis, 2017) and decreased muscle strength as a result of muscle weakness. (Chiles *et al.*, 2014) Previous studies revealed that patients with diabetic peripheral neuropathy suffer from a decline of balance performance and postural instability. (Camargo *et al.*, 2015)

Type 2 diabetic patients often exhibit impaired balance and gait dynamics, and are at a greater risk of falling. (El Bardawil *et al.*, 2013) Balance impairment in patients with diabetic peripheral neuropathy were found with increased range of dynamic postural sway

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indicating an impairment of balance control. (El Bardawil *et al.*, 2013; Brown *et al.*, 2015) The potential risk of falling for these patients is due to an increased dynamic balance sway, in addition to an increase in muscular effort to maintain balance. (Andreassen *et al.*, 2006)

Various studies support the view that gait dysfunction, fall risk and disability in those with diabetes may not be only a consequence of DPN and/or musculoskeletal impairment but also a function of cognitive problems. (Rucker *et al.*, 2014; Kelly *et al.*, 2013; Ko *et al.*, 2011) Cognition defined as a collective term for a range of higher brain functions, is a combination of multiple domains (e.g., attention, memory, visual-spatial ability, executive function [EF]) that work simultaneously to process information during functional tasks to maintain balance and prevent falling. (Blackwood *et al.*, 2016) The majority of cognitive functions are based in the prefrontal cortex. (Blackwood *et al.*, 2016) The role of the prefrontal cortex in cortical control of locomotion seems to be altered in older adults with diabetes (Holtzer *et al.*, 2018) and it is theorized that cognitive dysfunction may be a contributing factor that affects mobility and balance in older adults with type 2 diabetes mellitus (T2DM). (Blackwood *et al.*, 2016; Holtzer *et al.*, 2018; Bridenbaugh *et al.*, 2015)

Recent studies illustrated that T2DM was associated with accelerated cognitive decline, (Biessels *et al.*, 2008; Jor'dan *et al.*, 2017; Jor'dan *et al.*, 2014) beyond what would be expected in normal aging. (Holtzer *et al.*, 2018) According to the results obtained from a recent study, cognitive training and dual-task training were beneficial at improving balance and walking performance and reduction in fall risk in older adults with balance impairment. (Khan *et al.*, 2018) Therefore, the aim of this study was to explore the effectiveness of a traditional sensory-motor program combined with cognitive dual-task training in improving postural stability in DPN elderly people. It was hypothesized that the addition of cognitive dual-task training to traditional sensory-motor program can get better improvement in postural balance in DPN elderly people.

Subjects, Materials and Methods:

Participants:

A total of 50 patients with DPN that referred to Endocrinology and Metabolism Center at Golestan Hospital were enrolled in this study (Ahvaz, Iran). A double-blinded parallel randomized clinical trial with two arms was conducted. Care provider, data collector and those assessing outcomes were blinded to intervention. The participants included in the study if they aged more than 50 years, had T2DM for more than 3 years, diagnosed with DPN, had a BMI under 30 and a Mini Mental Scale Examination score more than 24 points. Exclusion criteria were the existence of active diabetic foot ulcers, history of vestibular disease, neurologic, rheumatologic or musculoskeletal disorders without association with diabetes affecting balance and gait, complete or partial amputation, using assistive devices, regularly taking medications that negatively affect cognition and consciousness (e.g. benzodiazepines).

Diagnosis of DPN was confirmed through the administration of the Diabetic Neuropathy Examination (DNE) and electro-diagnostic studies of tibialis and proneal nerves. Through a balanced randomization process, the patients were matched based on age and sex and were randomly assigned to experimental group (EG, n=25) and control group (CG, n=25). All protocol items including intervention delivery and data collection were done in Rehabilitation Sciences Faculty of Ahvaz Jundishapur University of Medical Sciences. Informed consent was obtained from all participants before the inclusion. Five patients from the CG and four patients from the EG did not attend the retest session for personal problems and one patient from EG discontinued treatment due to glycemic coma (Fig.1). The protocol was approved by Human Research Ethical Committee of the relevant university (IR.AJUMS.REC.1395.761). The study has been registered at a local Trial Registration (IRCT20160710028865N1).

DPN assessment

Diabetic Neuropathy Examination (DNE) scale was applied to corroborate the presence of DPN which was a valid scale with a high discriminative power between patients with and without DPN. (Ghanavati *et al.*, 2012) DNE is a hierarchical scoring system to diagnose DPN, and contains 2 motor (strength of quadriceps femoris and tibialis anterior muscles), one reflex (triceps sural), and 5 sensory (pin-prick sensation of index toe, and pin-prick, light touch, position and vibration sensation of the great toe) tests scored as 0 (normal), 1(decreased but present for sensation and reflex tests and grades of 3-4 for strength tests); 2 (absent for sensation and reflex tests and grade of 0-2 for strength tests). The overall score was 16 and a rating higher than or equal to 3 was indicative of the existence of DPN. The higher the score, the more severe the damage in each of the items. (Ghanavati *et al.*, 2012; Meijer *et al.*, 2003)

Equipment:

The Biodex Balance System (Biodex Medical Systems Inc, USA) platform is an important instrument for assessing postural stability and risk of falls in the elderly. (Garcia *et al.*, 2017) The BBS consists of a mobile platform that tilts in all directions with 8 levels of difficulty. Level 8 is the most stable, and level 1 is the most unstable setting. The platform provides an objective assessment of balance using three indices: the overall stability index (OSI), an anteroposterior stability index (APSI), and a mediolateral stability index (MLSI). These indices are calculated according to the degree of platform oscillation; smaller values indicated that the individual had good stability. (Eftekhar-Sadat *et al.*, 2015; Akbari *et al.*, 2012) This device also was used to assess the limit of stability (overall, forward and backward). The reported inter-examiner reliability coefficients were 0.77 and 0.99. (Garcia *et al.*, 2017)

The current study`s protocol was performed with stability level at 7. To measure postural stability, each participant was instructed the form of test to be run, and encouraged to hold the cursor in the middle of a target circle of monitor. A familiarization test was given to minimize the effects of learning, followed by 2 consecutive tests with 20 sec in total and 10 sec between each of them. The mean of two tests was calculated and the results were considered. (Eftekhar-Sadat *et al.*, 2015; Akbari *et al.*, 2012; Almeida *et al.*, 2017)

Treatment protocol:

Treatment was given for 3 days/a week for up to 8 weeks. The method of intervention delivery was face-to-face. Intervention provider had the degree of PhD of physiotherapy. Participants in both group, received TENS current (FM wave, 150 Hz, 20 Min). (Thakral *et al.*, 2013; Najafi *et al.*, 2013) In control group, each session was consisted of a warm up (5 Min) including stretch of calf and toe muscles, followed by a weight-bearing exercises (25 Min) including step up and down, step climbing sideways, one leg stance, heel rises, toe rises, step backward, knee lifts while seated, and 5 minutes cool down. All the tasks were progressed according to the published studies to maximize the progressive improvements. The WB exercises included in this program were adapted from exercises used in prior intervention that improved strength and gait in those with peripheral neuropathy. (Kruse *et al.*, 2010; Mueller *et al.*, 2013) Activity performance was supervised by a physical therapist.

To evaluate the net effect of dual-task exercise, we added motor-cognitive tasks as our dual-task intervention to the sensory-motor exercises. Thus, the patients in experimental group were encouraged to perform weight-bearing exercises the same as the control group combined with cognitive dual-task (CDT) training (15 Min). CDT training included walking on exercise mat in different pattern (5 Min), standing on balance board within parallel bar with opened-eyes (5 Min) and with closed-eyes (5 Min) conditions while performing arithmetic, verbal fluency, letter fluency and question-response dual-task. The order of exercises were randomized for each patient.

Sample size:

According to achieved results from previous study (Akbari, *et al.*, 2012) and counting 10% drop of , Power analysis revealed that sample size was 25 subjects for each group. At the end of our study, 5 patients in each group were missed for retest.

Statistical analysis:

Test of normality (kolmogorov-smirnov Test) was used before applying statistical analysis, and it showed that data were normally distributed, so we used a parametric test. Within group comparison between pre and post values was performed using paired-Sample T Test for paired (matched) samples. Comparison of numerical variables between the study groups was carried out using Independent-Samples T Test. P values less than 0.05 were considered statistically significant and less than 0.01 were considered highly significant. All statistical calculations were carried out using computer program SPSS version 22.

Results:

General demographic data

Descriptive analysis of the demographic data the age, BMI, duration of illness, Fasting Blood Sugar, HbA1c, Mini Mental Scale Examination, Geriatric Depression Score of patients with type 2 diabetic peripheral neuropathy in the two groups had no significant difference. Patients in the two groups exhibited significant difference in total neuropathy scores.

Postural stability

Initial analyses revealed no statistical differences between groups in all sway indices at baseline. A significant decrease of postural stability indices within the two groups was detected after training (*Table 2 and 3*), while the most decrease was observed in experimental group. The most significant postural stability improvement was shown in experimental Group compared to control Group expect Medio-Lateral stability index ($p<0.194$) *(Table 4).*

Table 1. Demographic data of groups

	Experimental Group	**Control Group**	**P-value**
Age (years)	57.5 (5.7)	57.2 (4.3)	0.83

BMI (kg/m^2)	26.1 (3.3)	26.7 (3.3)	0.55
Disease duration (years)	13.1 (8.4)	14.3 (8.4)	0.67
FBS (mg/dL)	202.1 (69.6)	221.65 (72.1)	0.39
HbA1C (%)	10.0 (1.4)	9.6 (1.4)	0.30
MMSE	26.7 (1.8)	26.2 (1.9)	0.41
GDS	7.3 (1.5)	8.2 (2.2)	0.16
DNE	7.9 (2.4)	6.0 (1.8)	**0.007**

BMI, body mass index; FBS, fast blood sugar; HbA1c, glycated hemoglobin; MMSE, mini mental state examination; GDS, geriatric depression score; DNE, diabetic neuropathy examination. All data are presented as mean (SD)

Table 2. The mean value of measurements in control group

	pre-training	**post-training**	**95% CI**	**effect size**	**p-value**
OSI	4.47 (1.57)	3.74 (1.70)	(0.16 , 1.30)	0.22	0.015
APSI	3.83 (1.39)	3.19 (1.60)	(0.21 , 1.08)	0.21	0.006
MLSI	2.77 (0.95)	2.22 (0.98)	(0.14 , 0.96)	0.27	0.011
OLoS	18.00 (18.63)	20.75 (20.11)	(-8.08 , 2.58)	0.07	0.294
FLoS	18.7 (20.20)	16.9 (15.87)	(-6.53 , 10.1)	0.05	0.656
BLoS	11.15(12.88)	13.70(14.81)	(-6.14, 1.04)	0.09	0.154

OSI, overall stability index; APSI, anteroposterior stability index; MLSI, mediolateral stability index; OLoS, overall limit of stability; FLoS, forward limit of stability; BLoS, backward limit of stability. All data are presented as mean (SD).

Table 3. The mean value of measurements in experimental group

	pre-training	**post-training**	**95% CI**	**effect size**	**p-value**
OSI	4.92 (2.40)	2.97 (1.45)	(1.06 , 2.83)	0.44	0.000
APSI	3.79 (1.71)	2.43 (1.24)	(0.77 , 1.94)	0.41	0.000
MLSI	2.65 (1.13)	1.73 (0.86)	(0.50 , 1.34)	0.42	0.000
OLoS	13.50 (13.45)	27.55 (20.55)	(-20.56 , 7.54)	0.37	0.000
FLoS	14.7 (15.85)	31.25 (24.09)	(-26.77 , 6.33)	0.38	0.003
BLoS	7.80(10.37)	20.60(15.43)	(-18.45, 7.15)	0.44	0.000

OSI, overall stability index; APSI, anteroposterior stability index; MLSI, mediolateral stability index; OLoS, overall limit of stability; FLoS, forward limit of stability; BLoS, backward limit of stability. All data are presented as mean (SD).

Limit of stability

A significant increase of limit of stability was detected only in experimental group after training ($p<0.003$) (*Table 2 and 3*) with less improvement in control Group compared to experimental Group ($p<0.02$) (*Table 4*).

Table 4. Comparison of difference means between groups

	Control Group	Experimental Group	CI 95%	*P*-Value	Effect Size
OSI	- 0.48 (1.30)	- 1.94 (1.88)	(- 2.50 , - 0.42)	0.007	0.41
APSI	- 0.45 (0.99)	- 1.36 (1.24)	(- 1.62 , - 0.18)	0.015	0.38
MLSI	- 0.40 (0.92)	- 0.92 (0.89)	(- 1.09 , 0.06)	0.079	0.28
OLOS	2.05 (9.85)	14.05 (13.91)	(4.28 , 19.72)	0.003	0.45
FLOS	0.2 (20.83)	16.55 (21.84)	(2.69 , 30.01)	0.020	0.36
BLOS	1.65 (6.18)	12.8 (12.08)	(5.01 , 17.29)	0.001	0.59

OSI, overall stability index; APSI, anteroposterior stability index; MLSI, mediolateral stability index; OLoS, overall limit of stability; FLoS, forward limit of stability; BLoS, backward limit of stability. All data are presented as mean (SD).

Discussion:

This study designed to evaluate the effects of an 8 weeks traditional sensory-motor exercises and sensory-motor exercises combined with cognitive dual-task training for improving postural stability in older adults with DPN. Our results demonstrated a highly significant improvement in postural stability and limit of stability in all directions for patients who received sensory-motor exercises in addition to cognitive dual-task training while in the control group, evidence of improvement was revealed only in postural stability indices.

There was no significant improvement of limit of stability in patients who received the sensory-motor exercises in control Group due to the inadequate attentional capacity. There was a significant improvement in postural stability of patients receiving the additional cognitive dual-task training over patients receiving the sensory-motor exercises program alone, as cognitive dual-task training accompanied with higher performance in cognitive (attention and executive functions), motor, and sensory functions in older adults. (Hamacher *et al.*, 2016)

Previous research supported a clear association between cognitive processing and falls in T2DM patients. (Hewston and Deshpande, 2016; Rucker *et al.*, 2012) Cognitive performance may minister as an index for fall-related mobility factors including balance abilities. Cognition involved the ability to assign and divide attention, the ability to respond to the spatial environment, and the ability to maintain temporary memory and online processing involved with walking (i.e., working memory). (Bridenbaugh and Kressig, 2015; Rucker *et al.*, 2012)

When the elderly with DPN were engaged in multiple tasks simultaneously, attention was divided between postural and cognitive tasks, their processing capability decreased and they performed one or both tasks poorly thus leading to decline in postural balance. CDT training was effective in improving postural balance. (Braue *et al.*, 2001) CDT training specifically divided attention domains of cognition that were associated with CDT processing. (Smith-Ray *et al.*, 2013) Thus, according to the results, it can be concluded that the utilization of cognitive dual-task training may effectively improve balance performance in older adults with DPN.

Our results were consistent with previous study results which combine cognitive dual-task training with other traditional exercises to influence balance abilities in older adults. (Hagovská and Olekszyová, 2016; Azadian *et al.*, 2016) Results from this study demonstrated a probable link between dual-task training, balance and gait. This presented a novel solution to a major public health problem by supporting the impact of cognitive dual-task training on mobility, as measured by balance parameters in older adults with DPN. This evidence was critical to understand whether methods for reducing fall risk in older adults with cognitive decline should begin to include cognitive dual-task training as one factor in a multifactorial approach or not.

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