International Journal of PharmTech Research
CODEN (USA): IJPRIF, ISSN: 0974-4304, ISSN(Online): 2455-9563
Vol.9, No.5, pp 151-159, 2016

Exercise Therapy Improves Planter Pressure Distribution in Patients with Diabetic Peripheral Neuropathy

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Abstract : Background: Patients with diabetic peripheral neuropathy are at an increased risk for developing foot ulcerations. The purpose of this study was to evaluate the effect of physiotherapeutic intervention including balance and gait training in addition to the stretching and strengthening exercises on planter pressure distribution in patients with diabetic peripheral neuropathy. **Subjects and methods:** Forty Saudi women with diabetic peripheral neuropathy were divided randomly into two equal groups, Study group: Their mean age (49.40± 3.35)years old and BMI (26.53±2.62) kg/m2.They were treated with physiotherapeutic interventions including stretching and strengthening exercise, balance and gait training beside their medical treatment. Control group: Their mean age (50.25±3.57) years and BMI (27.16±3.79) kg/m2.were treated by their medical treatment only. A capacitance-based pressure platform was used for detecting the pattern of planter pressure and A monofilament to check for sensory disturbance, **Results**: Within group comparison of the mean values of peak planter pressure and contact areas measured under the heel and metatarsal heads revealed that there is a significant difference between the baseline and follow up measurements ($p<0.05$)compared with control group. **Conclusion**: Physiotherapeutic intervention may prevent the diabetic foot ulceration in patients with diabetic neuropathy supported by significant changes in peak plantar pressure distribution and foot contact area.
Key words: Diabetic peripheral neuropathy-Foot ulcer- Planter pressure- Exercise therapy.

Introduction

Diabetic foot complications represent one of the main causes of both mortality and morbidity among the diabetic population. These complications may lead to meaningful physical, physiological and financial problems for the patients andsociety[1]. Diabetic peripheral neuropathy (DPN) is one of these complications. Its prevalence ranges from 13 to 68% among diabetes populations. A higher incidence of DPN was observed among Saudi population with diabetes, compared to the internationalprevalence[2,3,4].

Developing foot ulcerations is the major risk among the population of with DPN. Persistent and poorly controlled hyperglycemia causes neuropathic and vascular abnormalities that leads to foot deformities and skin breakdown[4,5]. The sensory, autonomic, and motor components of the nervous system are usually affected with loss of protective sensation, anhydrosis, and intrinsic foot muscle weakness and atrophy[6].

Muscular atrophy has been found to occur in intrinsic foot muscles before clinical diagnostic criteria were seenin DPN patients. This finding may partially explain the pathophysiological mechanism of DPN-induced foot plantar pressure abnormalities. With diabetic neuropathy, foot plantar biomechanical variations were closely correlated with lower limb paresthesia and contraction abnormalities of lower-limb extensor muscles[7]. In addition, reduced joint mobility increases the risk for subsequent ulceration[8,9].

Consequently, plantar pressure distribution is heterogeneous and characterized by overloading of anterior regions, unloading of toes and hallux[10,11], and a reduced role of lateral forefoot and toes in the foot rollover during stance phase[12].

Daily weight-bearing activity has been proved to decreased risk of foot ulceration in patients with insensate feet when compared with those who are less active, especially if there is minimal variation in their day-to-day activity pattern[13,14,15].A progressive walking program has been reported to conserve foot and leg muscles and make tissues of the foot plantar more tolerant to stress and less likely to laceration[13].It was also reported that moderate intensity aerobic exercises have a valuable role to prevent the progression of DPN in type 2 diabetes[16].Additionally, stretching, strengthening, and functional foot and ankle exercises provided significant effects on foot rollover, pressure redistribution in foot areas that are known to exhibit reduced participation in patients with DPN(heel, lateral forefoot, hallux, and toes) [17].

Studies that have illustrated positive influences of foot and ankle exercises among patients with DPN are not randomized controlled trials, and others reported a short duration of therapies, so there is no enough data to prove the effectiveness of such interventions. Additionally, previous studies focused on the ankle and foot exercises either stretching or strengthening leg and foot muscles while ignored the balance and proprioceptive training. To the best of our knowledge our study is the first to search in this area for the people in northern Saudi Arabia.

The aim of this study was to detect the effect of physiotherapeutic interventions including stretching and strengthening exercises for the ankle and foot in addition to balance and gait training for patients with diabetic poly neuropathyon pattern of planter pressure distribution.

Subjects and Methods

Subjects: Forty Saudi women were involved in this study, their age ranged from 45-55 years old. The patients were recruited from the diabetes out-patients' clinic at king Khalid Hospital, Hail, KSA. All patients were with a clinical diagnosis of peripheral diabetic neuropathy. Patient recruitment was conducted with an attempt to match the anthropometric characteristics such as body mass, height, body mass index, shoe size and age in addition to the duration of illness ranged from 5-15 years. The practical part of the study was performed in the outpatient physical therapy department at king Khalid Hospital, Hail, KSA.

The inclusion criteria 1) all patients were clinically diagnosed with diabetes(type 2) with duration of illness from 5- 15 years. 2) were diagnosed as peripheral diabetic neuropathy.3) With a body mass index (BMI) ranged from 25-29.9 kg /m^2. Exclusion criteria 1) history of rheumatoid arthritis, congenital deformities of the foot, Achilles tendinosis, post-traumatic deformities of the foot. 2) previous foot surgery, cardiac or pulmonary condition interfering with study procedures, 3) a history of circulation problems or deep vein thrombosis. 4) Patients with diabetic open foot ulcers, Charcot arthropathy confirmed by radiography.

Subjects were divided into two groups; study group: (n=20) performed strengthening and stretching exercises to ankle and feet beside balance and gait training for 8 weeks(3 sessions/week), Control group: (n=20), did not participate in exercises and took their medical treatment.

Material:

Evaluation Equipment

- A calibrated medical scale (27284 SECA 756 made in Italy) was used to weigh subjects in kilograms mechanically (500g to 150 kg) with height rod - (60-200 cm) to calculate body mass index for each subject

- Semmes-Weinstein monofilament (6.65 Model A83522, Germany) was used for measuring diminishing protective foot sensation. Including 2.83, 3.61, 4.31, 4.56, 5.07, and 6.65 monofilaments.
- A capacitance-based pressure platform (emed-q100, GmbH, Novel Munich, Germany) was used for detecting the pattern of planter pressure. Reliability of the platform has been proved by[18].

Therapeutic intervention;

The therapeutic sessions were divided into four blocks of exercises, characterized by the main objective of each exercise group. They were: (a) gain of foot and ankle ROM, (b) improve foot and ankle muscle strengthening, (c) improve balance, (d) gait training.

Methods

Before Starting the Study, the Following Were Performed

- The procedures and the study protocol were explained in details for each subject before the initial assessment.
- A signed written term of free and informed consent that was approved by the ethics committee of the local institution
- Explain signs and symptoms that when occurred the patient must stop exercise or decrease the intensity as case of: chest pain, dizziness, headache, confusion, sever fatigue and noticeable change in heart rate or increase of blood pressure.
- Before starting the exercise program, a complete medical history was taken and physical examination was done by a physician for all subjects
- Each subject of both groups passed through the following steps of measurements by the physician and the physical therapist recorded at the beginning and the end of the total study period (8 weeks)

Measurement of Body Weight and Height:

Each subject's height was measured in centimeters**.** Then the BMI was calculated resulting from mass in kilograms and height in meters using the following formula: BMI= weight (Kg) / [height (m)]^2 [(19)].

Sensory examination:

The monofilament was held perpendicular to the patient's feet. It was pressed against the foot, increasing the pressure until the monofilament bends into a **C** shape for about 1 second. The patient had to sense the monofilament by the time it bows then pressed to the skin, so it buckled at one of two times. The patient was asked to identify at which time she was touched. The monofilaments generate a reproducible buckling stress. The higher the value of the monofilament, the stiffer and more difficult it is to bend

Measurement of planter pressure distribution

After demonstration, participants were asked to walk on barefeet across the platform at a walking speed same as the usual gait [20,21]. The participants were asked to focus on a rounded sticker fixed on both directions of walking at the same level to standardize gaze away from the pressure platform during measurement. As we used a long walkway, participants were asked to take four steps before hitting the platform and continue afterward. These procedures were repeated until five passes were detected (five recordings of right foot). A trial was repeated if the foot is placed near to or on the edges of the platform.

Analysis of the peak pressure and contact area were recorded as the foot was divided into 6 regions: hind foot, first metatarsal, second metatarsal, third metatarsals, forth metatarsals, fifth metatarsals. The Novel foot report (emed-q100, GmbH, Novel Munich, Germany) was used to provide the basic information about a patient and the pressure measurement results in one report. The absolute peak pressure values, the contact area values were determined from the platform with a real size plantar pressure printout. The base line measurement was done immediately after randomization and a follow up measurement was completed eight weeks after the first measurement.

Training Program

For the study group (G_1), the physiotherapeutic sessions were applied 3 times a week for 8 weeks. Each session lasted 60 minutes. Each session was divided into four blocks of exercises beginning with 10 minutes of patients' education each session about the importance of foot care and exercises. The objectives of each exercise group are: gaining of foot and ankle ROM for 10 minutes, strengthening dorsiflexors, evertors and invertors muscles of the foot and ankle muscle for 15 minutes , Balance and functional exercises for foot and ankle lasted for 15 minutes consisted of stance on heel/toes, tandem stance, one leg stance, forward and backward perturbations and gait training included side and forward walking alternated with functional strength and endurance exercises (sitting to standing, walking up and down a step, stair climbing) beside restoring normal gait pattern that lasted for another 10 minutes. Each session contained exercises from the four groups. Gradual and progressive difficulty were offered to the patient according to their tolerance, beginning with sand bags weighted 1.5, then 2 kilo till maximum 4 kilos [22] respecting any limitation due to pain and/or decrease in performance during execution.In each session, the exercises were performed following an order that starts with the passive exercises, progresses to active, and finishes with walking and functional skills. During all exercises, proper alignment of the segments (no movement compensations are allowed) were maintained. During weight bearing exercises, additional care was taken to maintain proper foot support: the toes should always touch the floor, avoiding hammering or clawing when possible, and the ankle should not be laterally tilted (with lateral deviations).

Statistical analysis:

Statistical analysis was done using SPSS (version 20.0; SPSS Inc., Chicago, IL, USA), and significance was set at $P \leq 0.05$ with 95% confidence interval for difference. Descriptive statistics were calculated to summarize the demographic characteristics of the sample and all outcome measures at baseline and follow up measurement. Within group comparison was done using paired sample t-test to show the difference between the baselines and follow up measurement with significance was set at $P \leq 0.05$ and 95% confidence interval for difference.

Results:

A total of 40women with diabetic neuropathy completed this study without any drop off. The mean values of the patients' age, weight, height, body mass index (BMI), and shoe size in each group is detailed in table 1. Paired t-test for the two groups revealed that there is no significant difference between the groups in age (t=1.163; p=0.259), weight (t= 1.128; p=0.273), height (t= 0. 472; p=0.642), BMI (t=1.770; p=0.093), and shoes size (t=0.597; p=0.242). and duration of illness (t=1.207; p=0.558).

Table 1:Demographic data and duration of illness of the patient's groups ($G_{1, 2}$) who participated in the study.

Variables	Mean± SD		*T*	*p*
	G1	G2		
Age (years)	48.8± 4.55	50.25±3.57	1.163	0.259
Weight (kg)	64.75 ± 8.14	67.25 ±7.76	1.128	0.273
Height (m)	1.58 ± .056	1.57±056	0.472	0.642
BIM (Kg/m^2)	25.68±2.19	27.16±3.79	1.770	0.093
Shoe size	38.35±1.59	37.80±1.70	0.597	0.242
DOI (years)	10.60±2.96	10.05±3.45	1.207	0.558

SD, Standard Deviation $P > 0.05$ = Non-significant $P \leq 0.05$= significant*
G1: group 1G2:group 2 DOI: Duration of illness

Table 2 compares the mean values of peak pressure recorded at the base line and follow up measures of the right foot in study (G_1) and control (G_2) groups (* significant differences).

Foot region	Study group				Control group			
	Mean±SD	*t*	*p*	% imp.	Mean±SD	*t*	*p*	% imp.
Hindfoot Pre	210.25±25.42	12.652	.001*	18.10	213.25±40.58	-1.336	0.197	1.29
Hindfoot Post	172.20±17.19				216.00±38.90			
MH1 Pre	202.85±29.23	12.667	.001*	18.34	202.35±35.32	-1.503	0.149	1.33
MH1 Post	165.65±33.40				205.05±37.57			
MH2 Pre	239.60±33.69	9.409	.001*	22.75	241.55±79.58	10.242	0.264	-1.80
MH2 Post	185.10±38.00				237.20±79.74			
MH3 Pre	218.90±39.99	10.486	.001*	17.31	223.05±71.75	0.702	0.491	-1.99
MH3 Post	181.00±33.75				218.60±74.07			
MH4 Pre	167.05±31.58	8.638	.001*	26.52	169.55±50.01	-0.578	0.570	1.03
MH4 Post	122.75±33.63				171.30±48.42			
MH5 Pre	119.20±35.60	5.426	.001*	23.20	120.85±31.58	-1.133	0.271	4.51
MH5 Post	210.25±25.42				126.30±34.07			

SD, Standard Deviation $P \leq 0.05$= significant* % imp.: Percentage of improvement MH: metatarsal head.

Table 3 compares the mean values of contact area recorded at the base line and follow up measures of the right foot in study (G_1) and control (G_2) groups (* significant differences).

Foot region	Study group				Control group			
	Mean±SD	t	p	% imp.	Mean±SD	t	p	%imp.
Hindfoot Pre	22.15±6.40	-2.795	.012*	16.02	19.85±4.39	-1.398	0.178	7.30
Hindfoot Post	25.70±4.28				21.30±3.96			
MH1 Pre	7.90±5.98	-5.409	.001*	48.73	9.50±3.26	1.732	0.099	-18.42
MH1 Post	11.75±4.30				7.75±3.38			
MH2 Pre	5.75±3.65	-6.453	.001*	54.93	6.60±1.69	0.637	0.531	-5.30
MH2 Post	8.90±4.11				6.25±1.91			
MH3 Pre	5.55±4.19	-9.404	.001*	81.98	7.55±3.76	-0.459	0.652	5.30
MH3 Post	10.10±4.17				7.95±2.92			
MH4 Pre	5.25±3.33	-7.464	.001*	63.80	6.85±3.88	0.483	0.635	5.84
MH4 Post	8.60±±2.60				6.45±2.94			
MH5 Pre	5.10±3.52	-16.709	.001*	90.19	5.95±1.35	-1.535	0.141	3.53
MH5 Post	9.70±3.18				6.80±2.91			

SD, Standard Deviation $P \leq 0.05$= significant* % imp.: Percentage of improvement MH: metatarsal head.

The mean values of the measured Peak Pressure (PP) in the right (Rt) foot of (G1) and results of within group comparison are shown in table 2. Comparison of the mean values of PP measured under the hind foot revealed that there is a significant difference between the two measurement ($p<0.05$). Comparison of the mean values of PP measured under the 1st, 2nd, 3rd, 4th, and 5th metatarsal heads revealed that there is a significant difference between the two measurement ($p<0.05$).

The mean values of the measured PP in the right foot of (G2) and results of within group comparison are shown in table 2. Comparison of the mean values of PP measured under the hind foot revealed that there is no significant difference between the two measurement ($p>0.05$). Comparison of the mean values of PP measured under the 1st, 2nd, 3rd, 4th, and 5th metatarsal heads revealed that there is no significant difference between the two measurements ($p>0.05$).

The mean values of the measured Contact area (CA) the right foot of (G1) and results of within group comparison are shown in table 3. Comparison of the mean values of CA measured under the hind foot revealed that there is a significant difference between the two measurement ($p<0.05$) compared to the control group. Comparison of the mean values of CA measured under the 1st, 2nd, 3rd, 4th, and 5th metatarsal heads revealed that there is a significant difference between the two measurement ($p<0.05$).

The mean values of the measured CA in the right foot of (G2) and results of within group comparison are shown in table 3. Comparison of the mean values of PP measured under the hind foot revealed that there is a non-significant difference between the two measurement ($p>0.05$). Comparison of the mean values of CA measured under the 1st, 2nd, 3rd, 4th, and 5th metatarsal heads revealed that there is a non-significant difference between the two measurement ($p>0.05$).

Discussion:

The results of this study show that the mean hind foot and forefoot PP have been decreased with increased contact area after application of the physiotherapeutic exercises. This can be attributed to the effect of foot and ankle exercises to increase range of motion (ROM) different joints of the foot which lead to restoring foot rollover during gait. Moreover, increasing intrinsic muscle strength is very crucial to decrease the risk of foot ulceration and prevent soft tissues strain. Increasing ROM and muscle strength, balance can be considered the essence of a good motor control of the ankle and foot.

These results are consistent with previous report which stated that limited dorsiflexion and subtalar motion restricted the foot's ability to absorb shock and transverse rotation. Therefore, increasing the risk of plantar ulceration in the insensate foot [23]. On the other hand, increasing ROM of foot segments could contribute to restoring normal foot rollover during gait [23].

These results contradict the findings of [24] who stated that lower leg muscle strengthening has no effect on redistribution of the plantar load in DPN. In this study, the authors focused only on the planter and dorsiflexors of the foot and ignored the role of intrinsic muscles of the foot and subtalar joint. This joint gives the foot ability of repeatedly transform from a flexible and shock-absorbent structure to a more rigid lever during each gait cycle.

Another contradiction with [25] who suggested that increasing muscle strength may increase forces on the forefoot and may contribute to increased ulceration risk via increased plantar pressure. This was shown through observations of a positive correlation between muscle strength and stiffness in individuals suffering from peripheral neuropathy as compared to aged-matched control group. In our study we focused only on increasing flexibility in addition to muscle strength of the dorsiflexors and planter flexors muscles. Moreover, we focused on normal posture of the foot during functional gait and balance training as a prerequisite for restoring normal rolling over of the foot.

In the same theme, Mueller et al., concluded that with improved muscle strength in the lower limb, especially the dorsal flexors, inverters and evertors, less pressure or stress is placed on the foot during the stance phase of walking, resulting in reduced risk of ulcer formation [26]. It was also reported that weakness of the intrinsic muscles of the foot and ankle flexors and extensors represents an independent risk factor for the

occurrence of plantar ulcers, leading to a less effective plantar load distribution. Strengthening and muscle function recovery could be reflected on planter pressure distribution during walking[26].

In this study, it was believed that patient education to the exercises sessions and the hazards of the foot ulcerations were very important and shared in patients' improvement. This is consistent with [27] who reported that a less patient education for foot disorders is one of the causes behind high incidence of foot ulcers among Saudi when compared to non-Saudi. This also in close agreement with previous studies which reported that brief educational program is effective in preventing diabetic foot ulcers in high-risk patients [28,29]. Moreover there are studies reported that increasing awareness of diabetic foot care as well as its preventive measures resulted in a 50% reduction in major amputation rates[30,31].

An important limitation of this study is the small sample size. Nevertheless, we were able to show that there is a significant decrease of planter pressure after application of exercise therapy. Further detailed studies including male and females are needed to examine the gender as an independent variable.

Conclusion*:*

It can be concluded that Physiotherapeutic interventions is effective in prevention of soft tissue strain and ulceration of the planter surface of the foot among diabetic patients.

Acknowledgement

The authors are deeply grateful for Dr. Mohamed E. Khallaf Assistant Professor, Department of Physical Therapy for Neuromuscular disorders and its surgery, Faculty of Physical Therapy, Cairo University, Egypt for his valuable scientific support.

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