DOI: 10.7860/JCDR/2025/74988.20686

Original Article

Physiotherapy Section

Effect of Aerobic and Foot Intrinsic Muscle Strength Training on Plantar Pressures and Spatiotemporal Gait Parameters in Type 2 Diabetes Mellitus: A Randomised Controlled Study

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ABSTRACT

Introduction: Type 2 Diabetes Mellitus (T2DM) is associated with microvascular and macrovascular complications. Among all the complications, foot complications are mostly caused due to altered plantar pressures, spatiotemporal gait parameters, balance deficits and impaired proprioception, which often results in fall-related injuries in such patients.

Aim: To analyse the effect of aerobic exercises on plantar pressures and spatiotemporal gait parameters in T2DM patients.

Materials and Methods: A randomised controlled study was conducted in Hail General Hospital and King Khalid Hospital in Hail City, Saudi Arabia from September 2023 to June 2024. A total of 140 patients with uncontrolled T2DM diagnosed aged between 30 and 65 years were assessed for peripheral neuropathy, both with and without clinical signs based on the Michigan Neuropathy Screening Instrument Index (MNSI). The control group received standard medical care (Antidiabetic medications prescribed by a physician and a Diabetic diet prescribed by a Nutrition Therapist), and the experimental group received identical aerobic exercise and specific intrinsic foot muscle exercise along with standard care, three times a week for three months. A descriptive analysis was conducted to determine the mean, standard deviation, and normality of the variables. The Mann-Whitney U test was applied for intergroup comparison. A p-value <0.05 was considered statistically significant.

Results: A statistically significant reduction in the average plantar pressure, forefoot both left and right and right hindfoot pressure in the intervention group was observed compared to the control group. These reductions were significant at the p-value <0.001 level. In addition, significant improvements were observed in the spatiotemporal gait parameters, including step duration, gait cycle duration and double stance duration with p-value <0.001.

Conclusion: This study indicates that intrinsic foot muscle exercises and standard aerobic exercises may have an additive effect in improving function and reducing plantar pressure in patients with diabetes.

Keywords: Michigan neuropathy screening instrument index, Peripheral neuropathy, Physiotherapeutic intervention

INTRODUCTION

The DM is a chronic non communicable disease that is burdensome to the health of the public and society as a whole. There has been an increase in the prevalence of diabetes in recent years as a result of factors such as sedentary lifestyles, unhealthy eating habits and obesity [1]. According to the International Diabetes Federation (IDF), the prevalence of DM has been on the rise in recent years. As of 2023, the IDF estimates that there are approximately 537 million adults worldwide are living with diabetes and the total number of people living with diabetes is projected to rise to 643 million by 2030 and 783 million by 2045 [2]. The prevalence of diabetes has nearly doubled since 1980, primarily due to lifestyle changes and the increasing prevalence of obesity. The number of people diagnosed with diabetes is increasing even faster in developing countries, especially in low- and middle-income countries [3]. Poor food habits and an unhealthy diet are also significant factors in the development of diabetes. There has been an increase in the consumption of processed foods, sugary beverages, and high-calorie snacks in our society. As a result of these dietary choices, the risk of developing diabetes increases [1].

Various macrovascular and microvascular complications have been linked to T2DM. Among these complications are neuropathy, retinopathy, renal failure and cardiovascular disease [4]. Neuropathy is a common complication of diabetes that affects the peripheral nerves, resulting in symptoms like numbness, tingling and pain in the extremities [5]. As a result of this, foot sensation and function may be affected, leading to altered plantar pressures. Patients with T2DM can experience increased pressure on specific areas of their feet, making them more susceptible to foot ulcers and infections [6].

The spatiotemporal parameters of gait can also be altered in individuals with T2DM. Changes in the timing and distance of steps during walking are indicative of this condition. An individual's overall stability and balance may be affected by these changes, thereby putting them at an increased risk of falling and suffering a fall-related injury [7]. It has been shown that increased plantar pressure under the metatarsals is associated with atrophies of the intrinsic muscles of the foot in recent years [8]. There is a strong association between these impairments and peripheral neuropathy, a condition in which the peripheral nerves are damaged. Healthcare professionals must have a clear understanding of this relationship to manage and treat foot-related complications [9]. The exact mechanisms of the association between increased plantar pressure and intrinsic muscle atrophy are not fully understood. Nevertheless, it is hypothesised that sustained overload on the metatarsals disrupts normal muscle function, resulting in damage to the muscle fibers and atrophy of the muscles. A comprehensive approach to treating T2DM involves physical exercise, a healthy diet, and appropriate medication. It is widely recognised that exercise is an essential therapeutic regimen

for managing DM [10]. Individuals with T2DM are highly encouraged to engage in aerobic exercises, such as walking, jogging, cycling, and swimming. As a result of these exercises, heart rate will increase, and cardiovascular fitness will be improved because of rhythmic movements blood glucose levels are lowered, insulin resistance is reduced, and insulin sensitivity is enhanced. Aerobic exercise also assists diabetics in losing weight, which is essential for managing their condition [11].

Even though there are guidelines that detail the method and procedure for exercising, the ongoing debate over exercise duration, frequency, and type reflects the complexity and individuality of physical fitness. It is important to consider personal factors, goals, and preferences. Research and evidence in the field of exercise science should assist in providing individuals with more personalised and effective recommendations as the field of exercise science advances [12].

Patients with long-term DM may suffer from atrophy of intrinsic foot muscles [13]. Increasing plantar pressures under the metatarsals are thought to be caused by this atrophy which may further progress into ulcers [14]. Despite extensive research in this field [8,15], there remains a significant gap in understanding of the role of aerobic exercise and intrinsic foot muscle training in alleviating foot pressure and improving spatial-temporal parameters of gait. Developing effective preventive and therapeutic strategies for diabetic foot care depends on an understanding of how exercise and targeted muscle training impact the feet. Therefore, this study aimed to analyse the effect of aerobic exercises on plantar pressures and spatiotemporal gait parameters in T2DM patients.

MATERIALS AND METHODS

A randomised controlled study was conducted in Hail General Hospital and King Khalid Hospital in Hail City, Saudi Arabia, from September 2023 to June 2024. All participants provided informed consent, and the research ethics committee approved the study (H-2-23-173).

Inclusion criteria: Male subjects with uncontrolled T2DM diagnosed between the ages of 30 and 65 years were assessed for peripheral neuropathy, both with and without clinical signs based on the MNSI [16]. Furthermore, subjects were required to have an Ankle Brachial Index (ABI) [17] value between 0.95 and 1.20.

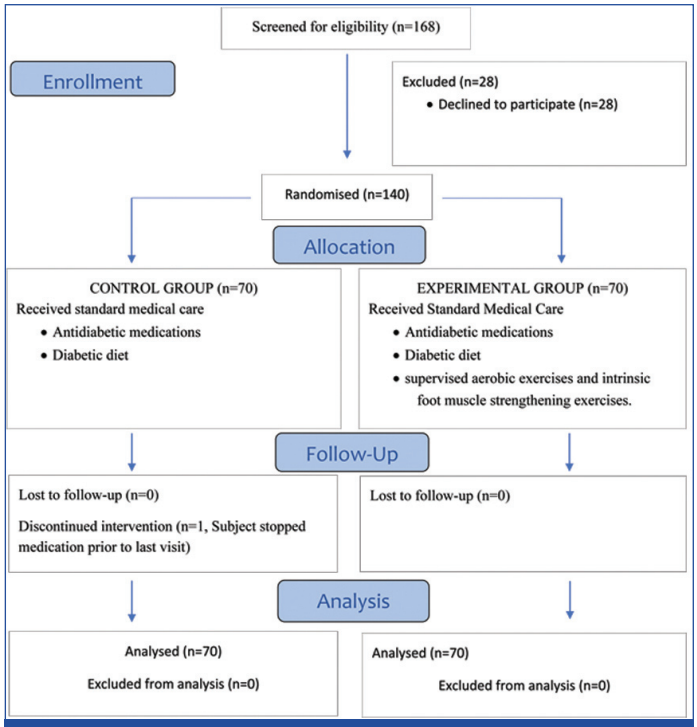
Exclusion criteria: Patients with neurological disease, hypothyroidism, postural hypotension, previous foot ulcers, retinopathy and other systemic diseases, and congenital and acquired foot deformities were excluded from the study.

Sample size: The sample size was calculated based on the Peak forefoot plantar pressure mean and standard deviation of 0.96±0.16, confidence interval of 80% with an effect size of 0.47, $N=2\sigma^2/d^2 (Z1-\alpha/2+Z1-\beta)^2$ [18].

N=168 subjects with a 20% non response rate,

Purposive sampling was used to recruit the participants diagnosed with T2DM, which provided a diverse and representative sample for the study. A total of 140 participants were included in the study, with 70 subjects in each group. As 28 participants did not complete the entire study; they attended the initial evaluation but did not return for the second evaluation, which took place after 12 weeks. [Table/Fig-1] shows the flowchart of the study.

All participants were diagnosed with T2DM according to American Diabetes Association guidelines [2]. Fasting and two-hour postprandial blood sugar levels, HbA1c levels were measured. Peripheral neuropathy was assessed using MNSI and was confirmed, differentiating between sensory and motor neuropathy through various tests. The 10 g Monofilament test evaluated pressure perception on the foot, followed by the Biothesiometer (Biothezi VPT from Kody Medical Electronics Pvt., Ltd., India) to assess the vibration pressure threshold. Finally, manual muscle testing was used for motor neuropathy assessment.



[Table/Fig-1]: Consort flowchart representation.

Exercise protocol: According to the American College of Sports Medicine (ACSM) guidelines, aerobic exercise was prescribed for T2DM [19]. The treadmill test method [20] was used to determine the appropriate exercise intensity. During the exercise sessions, intensity was set between 40% and 60% of the Heart Rate Reserve (HRR). The Rating of Perceived Exertion (RPE) scale, which ranges from 6 to 20, was utilised to gauge exertion levels. Both the experimental and control groups were prescribed supervised moderate-intensity exercise. Each exercise session was scheduled for 30 to 60 minutes, three days a week, over 12 weeks.

In addition to aerobic exercise, the experimental group was provided with a specific set of exercises targeting the foot muscles. These exercises included toe curls, ankle inversions, and eversion of the intrinsic foot muscles. Participants in the experimental group performed these exercises twice daily, completing ten repetitions per set with a ten-second hold between each repetition [21]. The control group received standard medical care which included antidiabetic medications prescribed by a physician and a diabetic diet prescribed by a nutrition therapist whereas, in the experimental group, participants received standard medical care which included antidiabetic medications prescribed by a physician and diabetic diet prescribed by a nutrition therapist along with supervised aerobic exercises and intrinsic foot muscle strengthening exercises.

The MNSI was used to assess sensory function, reflexes and foot ulceration related to neuropathy. Scores can reach up to 13 points, with higher scores indicating more symptoms. Items 1-3, 5-6, 8-9, 11-12, and 14-15 each score one point. Answers of “no” to items 7 and 13 also score one point. Items 4 and 10 measure circulation and anesthesia and are excluded from scoring. Patients scoring over 2 points in the clinical portion are considered neuropathic [16].

Plantar pressure analysis: For plantar pressure analysis, the eMed® platform measures pressure under the feet. Subjects stand barefoot on the platform for 20 seconds while maintaining a fixed gaze. The average plantar pressure and pressure distribution between the forefoot and hindfoot are assessed [22].

Spatiotemporal gait analysis using foot pressure-sensitive walkway: The Zebris Rehawalk (Zebris Medical, Isny, Germany) system was used to perform this analysis. The system utilises the innovative H/P-COSMOS technology.

A sensor system (FDM-THM-M-2i (Zebris Medical, Isny, Germany), 120 Hz, sensor area: 111.8×49.5 cm, 3,432 sensors) is installed on this walkway that measures the pressure exerted by each foot during the gait cycle. The subjects were instructed to look ahead and walk on the platform at a comfortable pace. Through the course of this procedure, step length, step duration, swing duration, gait cycle duration, double stance duration was recorded.

Step length is the anterior-posterior distance from the heel of one footprint to the heel of the opposite footprint. Step duration is the Time elapsed from initial contact of one foot to initial contact of the opposite foot. Swing duration is the time elapsed between the last contact of the current footfall to the initial contact of the next footfall of the same foot. Double stance support is the sum of the time elapsed during two periods of double support in the gait cycle [23].

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences (SPSS) version 26.0 was used to conduct statistical analysis. A descriptive analysis was conducted to determine the mean, standard deviation, and normality of the variables. The mean and standard deviation of continuous variables were calculated to summarise them. The Mann-Whitney U test was used to assess the differences between the groups. A p-value of <0.05 was considered statistically significant.

RESULTS

In the control group, there were 70 subjects with a mean age of 52.69±9.08 years, Body Mass Index (BMI) was 23.46±2.63 kg/m^2 and duration of T2DM was 7.51±3.52 years. In the experimental group, there were 70 male subjects with a mean age of 52.53±7.09 years and a BMI was 24.33±3.87 kg/m^2, duration of T2DM was 7.48±4.68 years.

A significant improvement in all biochemical characteristics and MNSI score was observed in the experimental group whereas similar parameters were getting worse except HbA1c in the control group even after standard medical care [Table/Fig-2].

Both average plantar pressure and heel pressure were significantly reduced in the experimental groups, compared to the control group with p-values <0.05. There was a strong statistical difference between the left hindfoot pressure of the control and the experimental group with p-value of 0.001. However, it is important to note that although the forefoot and peak plantar pressure in the experimental groups were reduced, no significant differences were observed among the groups themselves [Table/Fig-3].

In the experimental group, significant changes in gait timing and movements of the legs and feet during the gait cycle were improved. All the temporal gait parameters were improved in the experimental group. Step duration was improved from 660 ms to 638 ms which directly impacted swing duration from 350 to 220. Increase in step length by 51 mm and total gait cycle duration was reduced from 560 mm to 325 mm with less time spent on double support from 286 ms to 215 ms with a p-value of <0.001 whereas in the control group, an opposite trend was observed in temporal gait parameters compared to the experimental group [Table/Fig-4].

Parameters	Control group		Experimental group		p-value
	Baseline (Mean±SD)	At three months (Mean±SD)	Baseline (Mean±SD)	At three months (Mean±SD)	
Fasting sugar (mg/dL)	151.00±18.0	175.00±20.91	182.50±21.81	128.00±15.3	<0.001*
Post Prandial Sugar (mg/dL)	247.00±247.00	257.00±30.72	200.50±23.96	168.00±20.08	0.004*
Glycated Haemoglobin HbA1c (%)	9.80±1.17	9.75±1.16	9.20±1.09	8.25±0.98	<0.001*
Ankle Brachial Index (ABI)	0.95±0.10	1.00±0.119	1.15±0.137	1.00±0.11	<0.001*
Vibration Perception Threshold right (V)	18.00±2.15	23.00±2.74	23.00±2.74	19.00±2.27	<0.001*
Vibration Perception Threshold left (V)	16.50±1.97	24.00±2.86	20.00±2.39	16.00±1.91	<0.001*
Michigan Neuropathy Screening Instrument (MNSI A)	4.67±2.11	6.67±2.11	5.74±1.85	4.41±1.13	<0.001*
Michigan Neuropathy Screening Instrument (MNSI B)	1.74±0.95	2.25±0.89	1.18±0.93	1.46±0.98	<0.001*

[Table/Fig-2]: Intergroup comparison of biochemical characteristics and peripheral neuropathy screening using Michigan Neuropathy Screening Instrument (MNSI).
*(p<0.05- significant); **Mann-whitney U test

Parameters	Control Group		Experimental group		p-value
	Baseline (Mean±SD)	At three months (Mean±SD)	Baseline (Mean±SD)	At three months (Mean±SD)	
Average pressure Right (N)	227.45±27.18	243.14±29.06	228.45±27.30	210.51±27.30	0.002
Average Pressure Left (N)	220.56±26.36	239.24±28.59	224.68±26.84	211.57±26.48	0.001
Forefoot pressure Right (N/cm^2)	30.4±72.54	33.75±2.82	30.94±2.58	28.24±2.36	0.001
Forefoot pressure left (N/cm^2)	28.59±2.39	32.11±2.68	29.06±2.43	28.00±2.12	0.001
Hind foot pressure right (N/cm^2)	35.74±2.99	35.62±2.98	34.92±2.92	33.75±2.82	0.081
Hind foot pressure left (N/cm^2)	32.11±2.68	72.56±2.72	33.30±2.78	30.58±2.55	0.001

[Table/Fig-3]: Effect of aerobic and intrinsic foot muscle exercise on plantar pressure at baseline and the 12th week between the control and the experimental group in Type 2 Diabetes Mellitus (T2DM) with neuropathy.
*(p<0.05- significant); **Mann-Whitney U test

Parameters	Control group		Experimental group		p-value
	Baseline (Mean±SD)	At three months (Mean±SD)	Baseline (Mean±SD)	At three months (Mean±SD)	
Step duration (ms)	620.00±7401	645.00±77.09	660.00±78.89	638.00±81.87	<0.001
Swing duration (ms)	335.00±59.56	370.00±63.75	350.00±61.36	220.00±74.1	<0.001
Step length (mm)	422.00±50.44	414.00±49.48	402.00±48.05	453.00±54.14	<0.001
Gait cycle duration (ms)	335.00±47.6	360.00±62.55	560.00±86.46	325.00±46.42	<0.001
Double stance duration (ms)	260.00±19.12	325.00±26.89	286.50±105.96	215.00±14.94	<0.001

[Table/Fig-4]: Effect of aerobic and intrinsic foot muscle exercise on foot spatiotemporal gait parameters at baseline and the 12th week between the control and the experimental group in Type 2 Diabetes Mellitus (T2DM).
*(p<0.05- significant); **Mann-whitney U test

DISCUSSION

In the present study, intrinsic foot muscle strength and aerobic exercises significantly reduced the plantar pressures, especially on both the left and right forefoot. A study by Sartor CD et al., analysed the kinetics and kinematics of T2DM subjects during 12 weeks of ankle foot exercises and gait training. This study was limited by not assessing small joint mobility, which is controlled by the intrinsic foot muscles [21]. While Kumar AS et al., found that individualised 12-week sessions were effective for changing gait biomechanics [24] which supports the present study with an aerobic exercise program where intrinsic foot muscle strengthening was added.

Studies documented that, atrophy of intrinsic foot muscles leads to clawing and hammering of the toes which further leads to anterior translation metatarsal fad pad [25,26]. A strong intrinsic foot muscle would have prevented clawing or hammer deformity by maintaining the fat pad in place to protect the metatarsal heads from high loads. As a result, shock-absorbing effects under the metatarsal heads were maintained, which decreased plantar pressures. In addition, exercise-induced glycaemic control and increased peripheral microcirculation following aerobic exercise and intrinsic muscle strength could also be other factors [27]. As nitric oxide is released, smooth muscle cells vasodilate, regulating vessel wall shear homeostatically in the untrained vessel. Increases in shear stress caused by exercise cause an increase in endothelial nitric oxide production and consequent vasodilation [28]. This maintains the normal functions of the muscle and skin to regulate perspiration. Besides preventing dry skin conditions, it also prevents fissures and calluses.

The impairment of gait and an increased risk for foot complications are well documented in individuals with long-standing T2DM [29]. There was a significant difference observed in swing duration, gait cycle duration, and double stance duration in the present study. These gait factors have been studied and found to be conservative, consisting of a high double support time, slower speed and shorter steps to ensure stability while walking in diabetic peripheral neuropathy [29,30]. Several aspects of gait were improved by aerobic muscles in the present study. Intense foot muscle exercises prevented toe deformities and maintained plantar fat pads. Oxygen is delivered to tissues more efficiently with active exercise, which improves abnormal perfusion and plasma viscosity. The role of exercise is to improve abnormal perfusion and plasma viscosity, which facilitate oxygen delivery. Physical activity enhances blood flow and oxygen delivery throughout the body through a variety of physiological reactions [31]. An increased heartbeat and blood flow increase cardiac output, which measures how much blood the heart pumps. A higher cardiac output allows for more oxygen-rich blood to be delivered to tissues. As a result of exercise, blood vessels relax and blood flow increases. Several vasodilator substances are released to relax blood vessels.

Blood profiles of all subjects were also significantly affected by aerobic exercises. A decrease in HbA1c values was observed in the experimental group after aerobic and intrinsic foot muscle exercises. Studies show that aerobic exercise reduces HbA1C levels more effectively than other types of exercise, a measure of diabetes long-term glucose control. Several studies have linked aerobic exercise and glycaemic control. In an eight-year clinical trial on 65 T2DM participants, HbA1C levels were significantly reduced with aerobic exercise interventions [32-35]. These studies support the current study findings, demonstrating that while resistance exercises were included strengthening the intrinsic foot muscles played a more significant role in reducing plantar pressures and, consequently, the risk of foot ulceration.

According to Umpierre D et al., both aerobic and resistance exercises reduced HbA1c levels by 0.73% and 0.57%, respectively [36]. In the present study, the experimental group also exhibited a reduction in HbA1c levels. Lower HbA1c levels can enhance glycaemic control, particularly in patients with poor control. To improve health and wellbeing, it is essential to manage blood sugar levels effectively and reduce associated complications.

The fasting blood glucose and HbA1c values did not improve despite the standard care treatment and dietary modifications provided to the patients in the control group of the present study. A possible reason for this lack of improvement could be the patients' non compliance with the treatment and no adherence to the dietary changes. Therefore, it is believed that a long-term supervised protocol may be necessary to achieve better results.

Limitation(s)

In this study, the results were obtained from participants in Hail, which limits the ability to generalise the findings to other regions or populations, such as adults living in rural areas. Additionally, since all participants were male, it is crucial for future research to include female participants as well. Furthermore, the data from this study was not analysed intragroup, which would have provided deeper insights into how the data varied within the groups.

CONCLUSION(S)

In conclusion, the results of the present study highlighted the importance of intrinsic foot muscle exercise for the management of T2DM. Strengthening intrinsic foot muscles will enable individuals to distribute plantar pressures more effectively and prevent foot complications. Exercising intrinsic foot muscles as part of a comprehensive exercise program can provide a valuable addition to care for individuals with this condition.

Acknowledgement

Author of this study acknowledges Primary health care and College of Applied Medical Sciences, Hail University, Hail, Saudi Arabia for providing the support and infrastructure to conduct the study.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Aug 21, 2024
- Manual Googling: Jan 04, 2025
- iThenticate Software: Jan 06, 2025 (13%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Aug 19, 2024**
Date of Peer Review: **Oct 07, 2024**
Date of Acceptance: **Jan 08, 2025**
Date of Publishing: **Feb 01, 2025**