ORIGINAL ARTICLE

Rejuvenating Mobility: Impact of Concurrent Exercise on Functional Claudication Distance and Vascular Health among Patients with T2DM-Associated PAD

Uroosa Amin[1], Qurat-ul-ain Adnan[1], Dr. Tauseef Ahmad[2]

College of Physical Therapy, Faculty of Allied Health Sciences, Ziauddin University[1], Dr. Ziauddin Hospital[2]

Corresponding Email: qurat.adnan@zu.edu.pk

Abstract

Background: Globally, the diabetes epidemic has increased in the general population over the last few decades. Despite the higher prevalence of Type-II DM, evidence about Diabetes-related vascular complications is scarce. Therefore, this study aims to determine appropriate exercise training in clinical settings effectively, reducing risk factors for T2DM-associated PAD patients.

Methods: At the Department of Rehabilitation Sciences of Dr. Ziauddin Hospital Karachi, a randomized, single-blinded, two-arm trial was conducted from July to September 2023. Eighty patients with T2DM-associated PAD were recruited and randomly assigned into two groups Using the sealed envelope approach: Group A (n=40) and Group B (n=40). For 12 weeks, participants in Group B performed Aerobic Training (AT), while Group A participated in Concurrent Training (CT) 3 times a week. Functional Claudication Distance (FCD) and VascuQol-6 were measured pre and post-12-week intervention for measuring functional capacity and vascular health.

Results: Findings revealed that CT training groups significantly improved FCD and VascuQol-6 after 12 weeks ($p<0.000$). Subsequently, findings showed that the CT group showed more significant improvement than AT in improving FCD ($p=0.013$, CT: pre: 203.33±1.78, post: 230.65±7.72, AT: pre: 203.08±2.2, post: 214.13±5.1) and VascuQol-6 ($p=0.0001$, CT: pre: 10.60±2.11, post: 19.88±1.24, AT: pre: 9.53±2, post: 14.33±1.97).

Conclusion: Patients' reported vascular health and FCD significantly improved by the CT than the AT group. Therefore, CT appears to be an exceptionally beneficial therapeutic strategy for the management of Fontaine's stage II, a PAD associated with T2DM.

Keywords: *Claudication Distance, Diabetic Vascular Complication, Peripheral Artery Disease, Type-2 Diabetes Mellitus, Vascular Quality of Life.*

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Introduction

Over the past few decades, more than 90% (537 million) individuals globally suffer from Type-II Diabetes Mellitus (T2DM), and it is expected to afflict 783 million by 2045[1]. In the Middle East and North Africa, Pakistan has the highest adult prevalence of diabetes, according to the International Diabetes Federation's geographical distribution[1]. Diabetes is a growing epidemic, which increases the need for healthcare services and costs[2]. Effective management measures are necessary since most diabetes-related consequences are linked to macro and microvascular problems[3]. An increased risk of physical disabilities is encountered by individuals aged 45 years and older who are most affected by insulin resistance, which is exacerbated by altered body composition and reduced physical activity[4]. Although diabetes is more common in low- and low-middle-income countries (LMICs), diagnosing and evaluating diabetes-related problems in these countries became more difficult due to the lack of population-based studies and data systems[2]. Although exercise is crucial to managing T2DM according to worldwide guidelines, its execution continues to be limited[5]. Therefore, preventing or delaying acute and long-term vascular problems in clinical settings is imperative, as delayed diagnosis deteriorates blood vasculature. According to the World Health Organization (WHO), the diabetes-associated global death rate increased by 3% between 2000 and 2019, with a notable 13% increase in LMICs[6].

The vasculature of the lower extremities is mainly affected by Peripheral Artery Disease (PAD), a frequent vascular consequence of diabetes. Atherosclerotic obstruction-induced blood flow restriction results in ischemia and endothelial dysfunction, which is a vicious cycle that governs the pathogenesis of PAD. This ultimately disrupts aerobic muscle metabolism by inducing skeletal muscle fibre denervation, atrophy, and altered myosin expression. Consequently, a reduced aerobic capacity exacerbates the condition by affecting walking, muscle strength, endurance, and overall Quality of Life (QoL)[7]. PAD is still underdiagnosed and undertreated, with a 5% prevalence in the 40–44 age range despite its substantial adverse effects on health[8]. Epidemiological studies conducted worldwide indicate that 20% to 26% of T2DM patients have PAD, which negatively impacts their health. Despite this, only 6% of primary-care doctors are aware of the management guidelines of PAD, which is alarmingly low7. After ten years of T2DM, there is a 40% chance of developing PAD, which is significantly correlated with diabetes consequences[9]. Therefore, a combination of pharmacotherapy and exercise is considered the standardized care for T2DM patients with PAD[10].

Furthermore, Supervised Exercise Training (SET) was strongly recommended by the ACSM and AHA as the first-line management for PAD. Revascularization is suggested when conservative interventions are ineffective. Exercise can maximize the therapeutic efficacy of diabetes-related PAD by delaying the onset of T2DM-associated complications[11]. Aerobic Exercise (AE) has historically improved blood glucose, subcutaneous fat, and lipid profile in people with diabetes. Furthermore, sufficient time and intensity of modified AE can reduce oxidative stress and improve muscle metabolism and HbA1C[11]. According to the existing evidence, the implementation gaps of AHA guidelines are most noticeable in scientifically proven treatments in PAD patients, avoidance of impractical revascularization, and awareness of PAD among healthcare providers and patients[12]. Exercise also has a significant clinical impact on the pathogenesis of PAD and is a therapeutically effective way to improve skeletal muscle blood perfusion and function. Walking regimens increase blood perfusion of lower limb skeletal muscles and serve as a viable therapy to reduce long-term vascular problems in T2DM; the evidence currently highlights a strong need for progressive and concurrent exercise (CE) and Patient-Reported Outcome Measures (PROMs) due to limited data on the efficacy and appropriateness of CE for better outcomes[13]. Furthermore, there needs to be more research comparing the effects of separate AE and CE on walking ability[14]. Hence, the current study investigates how these exercises affect Functional Claudication Distance (FCD) and disease-specific Vascular Quality of Life (VascuQol-6).

In patients with T2DM-associated PAD, CE can have twice the effects at different intensities by the compensatory mechanisms of both forms of exercise[13]. Furthermore, it was found that CE for eight weeks, combining resistance and aerobic training in the same training session, was more successful in increasing muscle volume, myogenic factor, and glycemic indices[14]. Its significance is evident by the dearth of data regarding exercise regimens for specific patient characteristics and the advantages of CT over alone aerobic exercise regarding FCD and VascuQol-6 among Asian-demographic diabetic patients with PAD. This study aims to Intending to lower risk factors for T2DM-associated PAD, efficiently select appropriate exercise training by incorporating individualized exercise programmes into the clinical settings.

Methodology

Data for a two-arm, single-blinded, randomized controlled study was gathered from July to September 2023 at the Department of Rehabilitation Sciences of Dr. Ziauddin Hospital, a well-equipped tertiary care centre funded by the researcher. The Ziauddin University Ethical Review Committee approved this trial (Protocol Ref#7170523HSPAT), which complies with the Declaration of Helsinki's guidelines for using human participants in research and registered in the Clinical Trials Registry (NCT06028399).

All patients were given verbal and written information regarding the trial before induction. After that, voluntary informed consent was acquired. For inclusion, T2DM patients aged 40-50 years persisting >10 years, baseline HbA1C of >6.6%, intermittent claudication (Fontaine Stage IIa), PAD (ABI: <0.9 at rest), a BP <160/105 mmHg, and a sedentary lifestyle as determined by IPAQ-SF (Category-1) were considered. Patients were excluded if they had a history of severe arthritis, diabetic foot (ulceration or gangrene), stroke, insulin-dependent, unstable cardiovascular diseases, cancer, any major surgery or revascularization within the previous year; if they were unable to follow the intervention protocol or visit thrice a week for exercise; or if their consent had been revoked. Every patient's right to withdraw from the trial and anonymity were upheld.

Using the SNOSE approach, 80 T2DM-associated PAD patients were randomly assigned to intervention groups. Patients were arbitrarily divided into Groups-A (n=40) and B (n=40). Following the patient assignment, appropriate instruction was provided regarding group exercises, rest periods, treadmill walking, and the use of thera bands, including information on band colour and progression criteria. Two outcome measures, i.e. FCD and VascuQol-6, were assessed at baseline and twelve weeks afterwards. For FCD, the patient walked on a 100-foot indoor track, and the claudication distance where the patient preferred to stop walking was assessed[15]. FCD has a reliability of 0.959 for assessing individuals with intermittent claudication[16]. The VascuQol-6 questionnaire evaluated patients with symptomatic PAD to assess their disease-specific Qol. Every question has a four-point rating system, with one being the lowest and four representing the highest. The ultimate score is the total of the individual components in the 6 to 24-point range. The VascuQol-6 exhibits great validity (AUC=0.754) and strong reliability (Cronbach-alpha=0.82)[17]. Under the therapist's supervision, each participant performed 36 sessions lasting 30 to 60 minutes thrice a week for 12 weeks. Training consists of 10–12 minutes of warm-up activities, an intervention regimen, and 10–12 minutes of cool-down exercises for both groups comprising static cycling and static stretching of hamstring, quadriceps and calf muscles. Patients' heart rates, blood pressures, and random blood sugar levels were measured before and after each session for 12 weeks—Borg's scale (6–20) measured patients' perceived exertion levels. Group-A performed CT (aerobic with resistance training utilizing an elastic resistance band within the same session) for the hamstring, quadriceps and calf muscles, adhering to the recommended weekly progression and rest periods as shown in Table-1. Group B followed the same weekly progression and exercise intervention of Aerobic training alone. For patients' safety, exercise termination criteria included the following: pale appearance, cool skin, sweating, altered pulse, hemodynamic imbalance due to limited perfusion, patient request to stop exercising, and ischemic limb pain that persisted after 10 minutes[12].

Table I- FITT protocol for Concurrent Training (CT) – Group-A

Aerobic Training Weekly Progression					
Weeks	**F**	**I**	**T**	**T**	**P- Pattern**
1-2	3 alternate days per week	40% THR	15 mins	Treadmill walking	Seated rest intervals of 2-3 minutes as symptoms occur and resume as symptoms alleviated
3-4			20 mins		
5-6		50% THR	25 mins		
7-8			30 mins		

9-10		60% THR	35 mins			
11-12			40 mins			
Resistance Training Weekly Progression						
Weeks	**F**	**I**	**T**	**T**	**V**	**P-Pattern**
1-2	3 days per week	60% 1-RM	Time to complete the set per major muscle	Elastic resistance band	1 set, 12 reps.	Rest interval of 2 minutes between each set of reps
3-4						
5-6		70% 1-RM			2 Sets, 10 reps.	
7-8						
9-10		80% 1-RM			3 sets, 8 reps.	
11-12						

F-frequency, I-intensity, T-type, T-time,
THR = HRmax x % intensity,
HRmax = 220 – age,
1RM was calculated for intensity progression as per the patient's capability.

All patients had examinations for FCD and VascuQol-6 after 12 weeks of intervention. After that, SPSS Statistical Software, version 22, was used to obtain data entry and analysis. The study employed descriptive statistics, such as frequency, mean, and standard deviations, to ascertain the participants' demographic information. For inferential statistics, data was normally distributed using the Skewness and kurtosis test. Therefore, the Paired T-test was used for the within-group analysis of the CT and AT groups concerning quantitative measures (i.e., FCD and VascuQol-6). The Independent T-test was used sequentially to compare post-mean values on comparable outcome measures between the two groups. Moreover, a $p<0.05$ significance threshold was considered into considered.

Results

Pre and post-intervention mean values of FCD were evaluated in both the CT and AT groups to calculate the mean difference of each group. The findings demonstrated that the CT group improved remarkably, with a mean difference of 27.32, whereas the AT group suggested a mean difference of 11.05, representing the distinguished effects of CT. Statistically, for analyzing the significance of intervention among patients with T2DM-associated PAD, a paired sample t-test was employed, assuming the normally distributed data. The analysis demonstrated that CT and AT groups significantly improved the HbA1C over the 12-week intervention period ($p<0.05$). The statistical values of both CT and AT to increase functional claudication distance among patients are depicted in Table-2.

Analysis revealed an average age of 46.75±3.59 for CT and 47.05±2.05 for the AT group, and the duration of T2DM for developing PAD is 14.82±2.23 for CT, whereas 12.73±1.92 for AT. Statistically, a paired sample t-test was employed, assuming the normally distributed data. Both groups significantly improved the FCD after the 12-week intervention. To ensure comprehensive hypothesis testing of normally distributed data, findings revealed that CT substantially improved FCD (p=0.017) and VascuQol-6 (p=0.0001) more than AT at 95% Confidence interval for observed values. Statistically, the findings of FCD revealed that the AT group improved with a Mean Difference (MD) of 11.05, whereas the CT group showed 27.32. For evaluating Patient-reported outcome measures, VascuQol-6 findings suggested that the AT group improved with an MD of 4.8, whereas the CT group showed a more significant MD of 9.28. These findings represent the considerable effects of CT over AT. An insight into the comparative effects of CT and AT in improving FCD and VascuQol-6 is further explained in Table-2.

Table-2 Comparison of intervention groups on FCD and VascuQol-6

Variables	Pre Mean±S.D CT (n=40)	Pre Mean±S.D AT (n=40)	Post Mean±S.D CT (n=40)	Post Mean±S.D AT (n=40)	p-value
FCD	203.33±1.8	203.08±2.2	230.65±7.7	214.13±5.1	0.013
VascuQol-6	10.60±2.11	9.53±2.00	19.88±1.24	14.33±1.97	0.002

CT- Concurrent Training
AT- Aerobic Training

Discussion

This research showed that T2DM-PAD patients treated three times a week for 12 weeks with Concurrent Training (CT) improved their VascuQol-6 and Functional Claudication Distance (FCD) more efficiently than those who received treatment with AT. Walking interventions are emphasized in several national and international guidelines. However, other forms of exercise, including cycling, could benefit T2DM-PAD patients by improving their symptoms[17]. Increased muscle perfusion following SET could be the source of higher plasma nitrite concentrations and disease recovery[10]. An extensively researched method for managing PAD patients is to use SET via a treadmill. Specifically, both groups had a statistically significant improvement in FCD and disease-specific Qol. However, CT prevailed over AT, showing a noticeable and clinically significant increase in patients' recovery. The results of a clinical study examining the effects of Aerobic (AER) or Concurrent (CROS) training on middle-aged T2DM patients revealed that, following a 12-week intervention period, AER showed a higher mean than the CROS group (AER= 626.7±39.9, vs. CROS= 502.4±28.5; p≤0.001) in walking speed[18]. These findings contradict our study, which demonstrated that 12-week CT increases FCD more than AT in patients with T2DM-

PAD. The different intensities of the suggested training regimens for each group were based on target heart rate and 1RM. The CT approach, involving AT on a treadmill and RT with a resistance band, seemed appropriate for these individuals. These contradictions might result from variations in the length and intensity of the exercise regimen across the trial groups and targeted population. Furthermore, 41 older adults with metabolic syndrome participated in a 12-week blinded clinical trial involving 50 minutes of strength training at 40-70% of 1-Max Repetition and 40 minutes of walking activities at 70-85% of HR max. During that time, CT (twice weekly) revealed an additional rise in the 6MWT (p=0.001)[19]. These walking distance results are consistent with our study, which showed that patients in the CT group had better FCD than those in the AT group. Numerous studies have indicated that CT may impede muscle strength and power[20-22]. Key findings from our study showed that it does not impair FCD, indicating increased muscle perfusion and strength. The T2DM patients who presented with macrovascular complications, such as PAD and functional impairments, are the cause of the heterogeneity in our study's findings. The current study prioritized the ACSM guidelines, which suggest moderate-intensity exercise with gradual progression to vigorous due to particular population factors19. Due to the smaller sample size and unknown age range at the time of inclusion and the age >60 years, these results were inconsistent with our study's findings[22]. Moreover, the resistance training dose response was negligible since they did not employ the 1RM test to quantify the training load. We hypothesized that CT would provide various additional benefits due to the synergistic effects of both training. The results of FCD and vascuQol-6 showed a considerable improvement in the CT group compared to AT, which supported our hypothesis.

Strengths, Limitations and Future Recommendations

Our findings demonstrate that in people with hyperglycemia and lower extremities vascular atherosclerosis, a CT intervention can reverse the long-term adverse effects concerning functional limitations and patient health status. Nonetheless, Time constraints were the main reason why participants declined to participate. The individuals' comorbidities and significant differences in baseline physical activity levels may also have affected recovery time. It is crucial to consider that the results might not apply to those with gestational diabetes, T1DM, or people with severe or asymptomatic baseline vascular dysfunction, which requires additional research. Future studies should examine the effectiveness of various exercise types, intensities, and volumes to reduce potential confounding factors. Long-term follow-ups, smokers, different PAD Fontaine stages, and insulin-dependent DM are all necessary to address the study's limitations and increase the generalizability of the findings in healthcare settings.

Conclusion

CT is a cost-efficient, clinically effective, and statistically significant intervention for patients with T2DM-associated PAD. Interestingly, CT significantly improved functional claudication distance and vascular Qol by using an elastic resistance Thera band, establishing it as a feasible and low-risk treatment approach for these patients.

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Conflict of Interest
None.

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None.

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AUTHORS' CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

Conception or Design: Amin A

Acquisition, Analysis or Interpretation of Data: Amin A, Adnan Q, Ahmad T

Manuscript Writing & Approval: Amin A, Adnan Q, Ahmad T

All the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.