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Anuraj VS
Department of Pain and Palliative Care, National Health Mission Trivandrum, Kerala, India

Saji VT
School of Physiotherapy, Co-Operative Institute of Health Sciences, Thalassery, Kerala, India

Correspondence
Anuraj VS
Department of Pain and Palliative Care, National Health Mission Trivandrum, Kerala, India

An experimental study on effectiveness of specific exercise protocol in the prevention of limited joint mobility, muscle weakness and reduced gait speed in diabetes patients

Anuraj VS and Saji VT

Abstract
Background: This study focus on the effects of resistance exercises alone and specific exercise protocol along with resistance exercise on limited joint mobility, muscle weakness and reduced gait speed in long term diabetic patients.
Design: Experimental study.
Participants: 30 diabetic subjects will be selected from the population who fulfill the inclusion and exclusion criteria by convenient sampling. These subjects will be distributed into two groups (15 in each group).
Intervention: Control group received resistance exercises to muscles around the ankle joint using theraband and Experimental group received a protocol consisted of a 12 week supervised training program along with resistance exercises. Treatment period was about 50-60 min in each session on 3 non-consecutive days a week. Pre-test value was taken on the first day before the session and post-test value was taken on the last day after the treatment.
Outcome measures: The Outcome measures used were Goniometer, Baseline push-pull handheld dynamometer and 10 m walk test.
Results: Statistical analysis of intergroup significance by independent sample t-test for Gait speed [t=4.289>table value, t=2.048], isometric strength of right and left dorsiflexion [t=3.196 and 3.102 respectively >table value, t=2.048], isometric strength of right and left plantar flexion [t=2.539 and 3.081 respectively>table value, t=2.048], ROM of right and left dorsiflexion [t=3.638 and 3.473 respectively>table value, t=2.048], and ROM of right and left plantar flexion [t- value=3.384 and 2.954 respectively >table value, t=2.048] reveals that experimental group shows significant difference between pre-test and post-test values of gait speed, ROM and isometric strength than in control group.
Conclusion: Experimental group who received specific exercise protocol and resistance exercises shows greater improvement on limited joint mobility, muscle weakness and reduced gait speed in long term diabetes patients than those in the control group who received resistance exercises alone.

Keywords: Diabetes mellitus, dynamometer, stretching, gait speed, ROM, exercises, physiotherapy, rehabilitation

Introduction
Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar. Hyperglycemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems [1]. Type 1 diabetes (previously known as insulin-dependent, juvenile or childhood-onset) is characterized by deficient insulin production and requires daily administration of insulin. Type 2 diabetes (formerly called non-insulin- dependent or adult-onset) results from body's ineffective use of insulin [1, 2].
The number of people with diabetes has risen from 108 million in 1980 to million in 2014. The global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014. Diabetes prevalence has been rising more rapidly in middle- and low-income countries [1]. According to the Lancet study, China, India and USA are among the top 3 countries with a high number of diabetic population [3]. Now diabetes is spreading among the middle class and poor at an alarming stage in India & Kerala is turning to be the world capital of diabetes [4].

Diabetic foot is a major and progressively expanding health problem which often leads to foot ulceration, lower limb amputation and an increased death rate [5]. Neuropathy, vasculopathy and infection are known to be the main etiological factors of diabetic ulcers [6]. There are several contributory factors such as limitation of joint mobility, muscle weakness, gait abnormalities, and foot deformities that altogether are responsible for turning a normal foot into one characterized by a major risk of ulceration [7, 8, 9]. Subjects affected by diabetes have muscular weakness, a deficit of balance and reduced mobility at the ankle, subtalar and first metatarsophalangeal joints which interfere with normal rollover of the foot during the gait, leading to orthostatic posture and walking abnormalities. These may cause abnormal distribution of plantar pressure and consequently and lead to higher risk of foot ulceration [10, 11]. Limited joint mobility is widespread in diabetic patients.[12] The ROM deficit in diabetic patient's joints is due to periarticular limitations of the muscles, tendons, joint capsules, ligaments and skin [13]. A reduction in the ROM in the affected joints can occur in just a few years after diagnosis, even in young patients [13, 14]. There are important relationship between polyneuropathy and muscle weakness, both leading to decreased muscle strength and leg muscle atrophy [15, 16].

A specific exercise protocol is designed which consists of a 12 week supervised training program to improve joint mobility, muscle strength and gait speed in diabetic patients [17]. Resistance exercises also found to be effective in diabetic patients [31]. Outcome measures used in the study are goniometer, handheld isometric dynamometer and 10 m walking test. ROM can be assessed with Universal Goniometer [18]. Handheld isometric dynamometer can be used to assess isometric muscle strength of ankle joint.[19] 10 m walking test is used to assess the gait speed. In this test gait speed is calculated from the time taken by the patient to cover 10 m distance which were recorded by stopwatch [20].

One of the long term effects of diabetes is peripheral neuropathy which leads to foot ulceration (diabetic foot) which is the leading cause of lower limb amputation. So this study is to find out the effect of specific exercise protocol along with resistance exercises and resistance exercises alone on joint mobility, muscular strength and gait speed in a group of long term diabetic patients and thereby reducing the risk factors for ulceration in diabetic foot.

This study focuses on the effects of resistance exercises alone and specific exercise protocol along with resistance exercise on limited joint mobility, muscle weakness and reduced gait speed in long term diabetic patients.

Methodology

In this study, 30 diabetic subjects were included from the population who fulfill the inclusion and exclusion criteria by convenient sampling. These subjects were distributed into two groups (15 in each group). Group A (control group) includes 15 diabetic patients, they received resistance exercises to muscles around the ankle joint using theraband and participants. Baseline data were obtained by using goniometer, isometric dynamometer, and 10 m walking test. Whereas in Group B (experimental group) which also included 15 subjects, received an exercise protocol consisted of a 12 week supervised training program along with resistance exercises. Joint mobility, muscular strength at the ankle and gait speed were measured in both control and experimental group before and after exercise therapy. Patients with severe systemic complication, with visual disturbances, with severe sensory deficit and history of lower limb injuries-orthopedic and neurological were excluded from study.

The research design used in this study is an Experimental study design. The total duration of the study is 12 weeks. During which control group and experimental group receiving treatment session on 3 non-consecutive days of a week. The study was conducted at the Academy of Medical Sciences, Pariyaramand Co-operative Institute of Health Sciences, Thalassery, Kerala, India.

The Subject were clearly instructed and made understood the procedure. The Ethical Committee of Co-Operative Institute of Health Sciences approved this study and written informed consent from all participants were taken.

Training Procedure: The training program consists of 5 phases**,**

First Phase: Warm-up Walking or cycling for 10 minutes (Fig-1). The bicycle saddle was lowered by 3 inches, and the patient's position on the seat was moved forward in order to induce greater ankle dorsiflexion.

Second Phase: Stretching muscles and tendons (Fig-2). The second phase of 25 minutes consisted in stretching muscles and tendons. The exercises were related to muscle and tendon structures of the spine, pelvis and lower limbs, performed while sitting and standing by step, wall bars and elastic bends (Fig: 3, 4). Program exercises included the following. Patients were required to perform a 20-second stretching followed by 20 seconds of relaxing, twice for each session. They were to rest for 1 minute in between the different exercises. Patients were then instructed to stretch and relax their muscles as they felt muscle tension without pain and thorough relaxation.

Third Phase: During the last 8 weeks of the program, consisted in exercises to stimulate the patient's proprioceptive sensitivity, postural control and orthostatic-dynamic balance. The patient was to perform frontal-lateral normal and high knee walks at different speeds in a straight line. In front of the mirror, the patient was to stand with both hands lightly supported on the wall bars to avoid falls, then stand on the heel, stand on one leg and do a foot rollover from the toe to the heel and conversely; then to repeat exercises with eyes open and eyes closed, with and without an unstable platform. Patients were required to perform the exercise for 20 seconds followed by 20 seconds of relaxing twice for each session. When a subject carried out the protocol correctly, the difficulty of the exercises was progressively increased.

Fourth Phase: 10-minute phase, during the final 6 weeks, consisted in strengthening exercises for different muscular groups, each exercise was to be performed with 8-12 repetitions and 1 minute of relaxation in between exercises (Fig-5).

Fifth Phase: During the cool-down patients were seated so as not to touch the ground with their feet, and used one foot at a time and then both feet to draw in the air the widest possible letters of the alphabet using the hallux. The last

step was for patients to be seated on the bench, and do shoulder circles, neck stretches and chin tucks.

Statistical Analysis: Data was cleaned and feeded in SPSS20.0 software. A Kolmogorov-Smirnov test was done to find out the normality. A Paired t test was used as parametric test to find out the intra group significance. Independent t-test was used to analyze inter-group significance.

Fig 1: Cycling (warm up)

Fig 2: Resistance exercises using theraband

Fig 3: Single leg standing

Fig 4: Semi squatting

Fig 5: Fore ward lunges

Results

The data were collected and cleaned and processed for analysis. 30 diabetic subjects will be selected from the population who fulfill the inclusion and exclusion criteria by convenient sampling.

Table 1: it shows the mean and standard deviation of age, height, weight and BMI of both control and experimental group.

Group		N	Minimum	Maximum	Mean	Std. Deviation
Control Group	Age	15	51.00	60.00	55.0667	2.96327
	Height	15	151.00	166.00	157.8667	5.01237
	Weight	15	58.00	72.00	66.4000	4.01426
	Bmi	15	25.40	28.10	26.6200	.77016
Experimental Group	Age	15	50.00	60.00	55.8000	3.25576
	Height	15	151.00	169.00	159.1333	5.89027
	Weight	15	60.00	75.00	67.6000	4.48490
	Bmi	15	24.70	29.80	26.7067	1.58090

Kolmogorov-smirnovand shapiro-wilk tests were prefprmed for checking the normality for intra group should significance of gait speed in control and experimental groups.

Table 2: Analysis of inter group significance of gait speed using independent sample t-test

	Mean	Std. Deviation	% change	95% Confidence Interval of the Difference		t- value	D. f.	Sig. (2-tailed)
				Lower	Upper			
Control group	15.2533	1.34317	12.57	1.389	3.930	4.289	28	.000
Experimental group	12.5933	1.99122	24.16					

From the above table through independent sample t-test, it is evident that significant value 0.000 which is less than probability value p=0.05 and calculated t-value=4.289 which is greater than table value t=2.048(d. f. =28); which indicates that there is statistical significant difference between the post-test values of GAIT SPEED in Control group and Experimental group.

Table 3: Analysis of inter group significance of isometric strength of right and left ankle dorsi flexion in control and experimental group using independent sample t-test

Variables		Mean	Std. Deviation	% change	95% Confidence Interval of the Difference		t-value	D. f.	Sig. (2-tailed
					Lower	Upper			
Isometric strength df of right	Control group	12.9667	1.493	15.77	.6343	2.898	3.196	28	.003
	Experimental group	14.7333	1.533	25.92					
Isometric strength df of left	Control group	12.7000	1.590	15.45	.5659	2.767	3.102	28	.004
	Experimental group	14.3667	1.342	26.02					

This table shows the independent sample t-test, it is evident that significant value 0.003 For Flexion of Right and 0.004 For Flexion of Left, both are less than probability value p=0.05 and calculated t-value=3.196 and 3.102 which are greater than table value t=2.048(df =28); which indicates that there is statistical significant difference between the post-test values of Isometric Strength Dorsi Flexion Right and Left test values in Control group and Experimental group.

Table 4: Analysis of inter group significance of isometric strength of right and left ankle plantar flexion in control and experimental group using independent sample t-test

		Mean	Std. Deviation	% change	95% Confidence Interval of the Difference		t-value	D. f.	Sig. (2-tailed
					Lower	Upper			
Isometric strength pf of right	Control group	15.3333	1.643	11.92	.3028	2.830	2.539	28	.017
	Experimental group	16.9000	1.734	19.57					
Isometric strength pf of left	Control group	14.9333	1.821	11.72	.6481	3.218	3.081	28	.005
	Experimental group	16.8667	1.608	21.05					

The table represents independent sample t-test, it is evident that significant value 0.017 For Flexion of Right and 0.005For Flexion of Left, both are less than probability value p=0.05 and calculated t-value=2.539 and 3.081 which are greater than table value t=2.048(df =28); which indicates that there is statistical significant difference between the post-test values of Isometric Strength Plantar Flexion Right and Left test values in Control group and Experimental group.

Table 5: Analysis of inter group significance of rom of right and left ankle dorsiflexion in control and experimental group using independent sample t-test

		Mean	Std. Deviation	% change	95% Confidence Interval of the Difference		t-value	D. f.	Sig. (2-tailed
					Lower	Upper			
Rom ankle df of right	Control group	12.5333	1.505	18.98	.8738	3.126	3.638	28	.001
	Experimental group	14.5333	1.505	32.92					
Rom ankle df of left	Control group	12.2667	1.486	18.71	.7656	2.967	3.473	28	.002
	Experimental group	14.1333	1.457	32.49					

From the above table through independent sample t-test, it is evident that significant value 0.001 For Flexion of Right and 0.002For Flexion of Left, both are less than probability value p=0.05 and calculated t-value=3.638 and 3.473 which are greater than table value t=2.048(df =28); which indicates that there is statistical significant difference between the post-test values of Rom Ankle Dorsi Flexion Right and Left test values in Control group and Experimental group.

Table 6: Analysis of intra group significance of rom of right and left ankle plantar flexion in control and experimental group using paired t-test

Group		Mean	Std. Deviation	% change	t- value	Df	Sig. (2-tailed)
Control group rom ankle	Pf right pre test	27.8000	2.93258	8.87	18.500	14	.000
	Pf right post test	30.2667	2.63131				
	Pf left pre test	27.5333	3.06749	7.99	15.199	14	.000
	Pf left post test	29.7333	2.98727				
Experimental group rom ankle	Pf right pre test	27.8000	2.39643	19.18	22.958	14	.000
	Pf right post test	33.1333	1.95911				
	Pf left pre test	27.7333	2.40436	17.30	27.495	14	.000
	Pf left post test	32.5333	2.13363				

From the above table through paired t-test, it can be seen that calculated value t=18.500 (sig0.000) for control group right, t=15.199 (sig0.000) for control left, t value=22.958 (sig=0.000) for experimental group right and t=27.495 (sig0.000) for experimental group left, all are greater than the table value t= 2.144 (df =14 at p=0.05),

Table 7: Analysis of inter group significance of rom of right and left ankle plantar flexion in control and experimental group using independent sample t-test

		Mean	Std. Deviation	% change	95% Confidence Interval of the Difference		t-value	D. f.	Sig. (2-tailed
					Lower	Upper			
Rom ankle p. f. of right	Control group	30.2667	2.631	8.87	1.131	4.601	3.384	28	.002
	Experimental group	33.1333	1.959	19.18					
Rom ankle p. f. of left	Control group	29.7333	2.987	7.99	4.741	.8584	2.954	28	.006
	Experimental group	32.5333	2.133	17.30					

From the above table through independent sample t-test, it is evident that significant value 0.002 For Flexion of Right and 0.006For Flexion of Left, both are less than probability value p=0.05 and calculated t-value=3.384 and 2.954 which are greater than table value t=2.048 (df =28); which indicates that there is statistical significant difference between the post-test values of Rom Ankle Plantar Flexion Right and Left test values in Control group and Experimental group.

When comparing the post-test values of gait speed, isometric strength and ROM of both control and experimental group through analysis of inter group significance: Gait speed shows calculated t-value=4.289 (>table value=2.048, df-28 at p=0.05) in independent sample t-test. Isometric strength of right and left dorsiflexion shows calculated t- value=3.196 and 3.102 respectively (>table value=2.048, df-28 at p=0.05), & isometric strength of right and left plantar flexion shows calculated t- value=2.539 and 3.081 respectively (>table value=2.048, df-28 at p=0.05) in independent sample t-test. ROM of right and left dorsiflexion shows calculated t-value=3.638 and 3.473 respectively (>table value=2.048, df-28 at p=0.05), & ROM of right and left plantar flexion shows calculated t- value=3.384 and 2.954 respectively (>table value=2.048, df-28 at p=0.05) in independent sample t-test. These results show that experimental group shows significant difference from control group in all outcome measures. Hence, we can reject the null hypothesis and accept the alternate hypothesis that, "there is significant effect on specific exercise protocol along with resistance exercises in the treatment of limited joint mobility, muscle weakness and reduced gait speed in long term diabetic patients".

Discussion

This study was conducted to find out the effect of resistance exercise alone and specific exercise protocol along with resistance exercise on limited joint mobility, muscle weakness and reduced gait speed in long term diabetic patients. Diabetic Peripheral Neuropathy (DPN) is a common chronic complication of diabetes mellitus that has been very challenging for clinicians for a long time. DPN results in reduction in joint mobility, muscle weakness and reduced gait speed. DPN also results in high public health costs and has a huge impact on the quality of life of patients when not treated properly. Prevention is still the most important way to avoid plantar ulceration and amputation, which is the most devastating endpoint of the disease.

Diabetic peripheral neuropathy affects up to 50% of people with diabetes. The feet are the main target of most of the sensory and motor complications. Limitation of joint mobility, muscle atrophy and reduced walking speed can be established in later stages of disease[5]. Tissue alterations around distal joints, such as thickening of joint structures, tendons and ligaments have been clinically observed in patients. These tissues contain greater quantities of collagen and are exposed to non-enzymatic glycosylation caused by hyperglycemia, reducing tissue elasticity. These alterations can result in foot rigidity which in turn causes reduction in walking speed. All these changes result in increase in plantar pressure, predisposing them to plantar ulcers[21]. The joint collagen structures respond to mechanical stresses to adapt to the types of movements and mechanical stresses. Stretching and exercising the joints pushing them to their limits and thus, inducing mechanical stress. This stress results in remodeling of the structures around the ankle joint and breakdown of collagen. Although it is not known if the remodeling of these structures is preserved in patients with diabetes mellitus, home exercise therapy has been suggested to improve distal joint mobility and walking speed [22].

Studies shown that the volumes of intrinsic and extrinsic foot muscles were halved in long term diabetic patients [23]. The strength of the lower limb muscles can be improved through muscle strengthening exercises by progressively increasing resistance [24]. Muscle remodeling in resistance training reflects a complex process of cell receptor interaction with different hormones and DNA-mediated production of new contractile proteins. Neural mechanisms

leading to strength gains can include recruitment of more motor units; motor units recruited more synchronously, and decrease in autogenic inhibition from the Golgi tendon organs [25].

In keeping these observations, these findings demonstrate that a period of 12 weeks of exercise therapy which is tailored to the subject's condition is able to improve ankle joint mobility, muscular strength and walking performance. Pre-test evaluation of control and experimental group shows that there is no significant difference between the groups before treatment. When analysis of intra group significance were done within the groups in both control and experimental, there shows significant difference between the pre-test and post-test values of gait speed, isometrics strength and ROM in both groups. But when the analysis of intergroup significance was done between the post-test values gait speed, isometric strength and ROM of control and experimental group; it is evident that experimental group shows significant improvement

Hence, the study reveals that specific exercise protocol along with resistance exercise shows greater improvement than resistance exercises alone in the treatment of limited joint mobility, muscle weakness and reduced gait speed in long term diabetic patients.

Limitations of this study includes small sample size which might affect the generalization of the results, less study duration, patients includes in this study were limited to those referred to the PMR departments of Co-operative institute of health sciences & Pariyaram Medical College and all measurements were taken manually and this may introduce human error which could affect the reliability of the study.

Based on the statistical analysis, it is suggested that the future studies should be modified to accommodate the following changes: Long term study must be carried out for more reliability and validity, Long term follow up is needed to evaluate whether there occurs any sustained or carry over effect after treatment. To establish greater efficacy of the treatment, the study should be undertaken in large scale randomized clinical trial that would include a large sample size and a longer follow up.

Ethics approval: The Ethics Committee of Co-Operative Institute of Health Sciences approved this study. All participants gave written informed consent before data collection began.

Competing/ conflicts of interests: Nil

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