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RESEARCH ARTICLE

A COMPARATIVE STUDY ON THE EFFECTS OF AEROBIC EXERCISE PROGRAM AND CONVENTIONAL ORAL THERAPY MEDICATIONS ON NON INSULIN DEPENDENT DIABETIC MELLITUS PATIENTS: A RANDOMIZED SINGLE BLIND STUDY

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ABSTRACT

Background and objectives: This study investigated the effects of an 8 – week supervised circuit training program with moderate intensity on the fasting blood glucose level of NIDDM patients of sedentary lifestyle over conventional oral therapy medications.

Method: 40 NIDDM patients aged 35-55 years volunteered for the study. Subjects were randomly assigned into exercise and diet group (n = 20) and conventional oral therapy group (n = 20). The exercise and diet group received 60 minutes of supervised circuit training thrice a week for 8 weeks along with a prescribed diet control. Subjects in the other group were only on conventional oral therapy medications. Measurements were taken on 1^{st} , 30^{th} , and 60^{th} day which include fasting blood glucose level.

Results: The results showed a very highly significant (p = 0.001) decrease in fasting blood glucose level. When both groups were compared the exercise and diet group was found to be more beneficial and effective than the conventional oral therapy medication group.

Interpretation and conclusion: Both conventional oral therapy medication and exercise and diet groups can be used in management of NIDDM. However in this present study it is seen that exercise and diet is more beneficial and effective as compared with conventional oral therapy medication in reduction of glucose levels and thus, reducing the need of oral medications.

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INTRODUCTION

Type 2 diabetes mellitus is commonly called Non Insulin -Dependent Diabetes Mellitus (NIDDM). It was previously known as maturity – onset or adult – onset diabetes. The etiology suggests that environmental factors play a role in development of NIDDM because the prevalence rate increases with obesity and aging. NIDDM is characterized by diminished insulin secretion relative to serum glucose levels and peripheral insulin resistance, both of which can be exacerbated by chronic hyperglycemia and improved by euglycemia. Individuals with the disease have abnormalities in both hepatic glucose production and glucose uptake in peripheral tissues. (DeFronzo, Simonson, & Ferrannini, 1982; Kolterman et al., 1981) Non insulin dependent diabetic mellitus patients are at increased risk of all cause premature mortality and death and many consider physical activity to be an integral component of diabetes management. Traditionally, exercise programs in type 2-diabetes have involved aerobic training regimens, consisting of repetitive large muscle group exercise aimed at improving cardio respiratory fitness and glycemic control. Type 2 diabetes is most common form of diabetes. In United States alone, an estimated 16 million individuals have diabetes mellitus, and in close to a third of them the disease is undiagnosed. A very majority (90%-95%) have type 2 diabetes formerly called NIDDM.

AGE (years)	U.S population with diabetes type 2
18 - 44	1.3 %
45 - 64	6.3 %
65 +	10.4 %

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The epidemiology of inactivity suggests that 24 % are completely sedentary with no physical activity over past months in survey conducted by National Survey – Health promotion in 1991⁵. There are numerous behavioral, physiological and psychological variables related to initiating and maintaining physical activities. A lack of time, injury etc is cited as a barrier to exercise and a common reason for stopping regular activity. 3 Regular physical activity has been regarded as an important component to increase longevity and overall quality of life. 4 Physical activities can help people with diabetic mellitus to achieve a variety of goals including increased cardio respiratory fitness, improved glycemic control, decreased insulin resistance and maintenance of weight loss.⁵ At rest, muscle cells like other cells in people with NIDDM are resistant to insulin, this prevents the uptake of glucose. During exercise however, it has been shown that the activation of muscle contraction actually facilitates the uptake of glucose much like insulin, by making the muscle cell more permeable or allowing to pass into the cells more easily. 6 The evidence at present suggests that it is during each bout of exercise insulin resistance is lowered. But to date longer term changes to insulin resistance have not shown. Those with NIDDM should therefore be encouraged to be frequently active, in order to help control their NIDDM.

Exercise helps the body to decrease insulin resistance and burn excess glucose. Regular exercise and diabetic diet also helps to improve blood cholesterol level and reduce stress. So many studies have been done individually on the effects of aerobic exercise on NIDDM patients to decrease and control the blood glucose level, but there was lack of study comparing between effects of aerobic exercise and oral therapy on NIDDM patients.

METHODS

The study design is a randomized single blind study where the independent variables are aerobic exercise and conventional oral therapy and Non Insulin Dependent Diabetic Mellitus as dependent variable. 40 patients in age group of 35 - 55 years who were diagnosed with non insulin dependent diabetic mellitus were randomly selected from the department of General medicine of K.S Hegde Charitable hospital, Deralakatte, Mangalore and private physicians from Mangalore, Karnataka. Inclusion criteria included Non-insulin dependent diabetic mellitus patients, sedentary group of people, Age group of people between 35 and 55 years, Patients with fasting blood glucose levels between 100 mg/dl and 200mg/dl. The patients who were excluded were patients with peripheral vascular diseases, Peripheral neuropathy, Soft tissue and joint injuries, Heart disease patients, Loss of proprioception. Tools used were stop watch, skipping rope, bench stepper, dumbbells of 1kg and 1.5kg. Out of 40 selected patients, 20 patients were grouped under the conventional group, where the patients were on oral medications. The other group of 20 patients is under aerobic exercising group and diet. The diet control was prescribed to the patients by dietician during the study. Prior to the administration of the variables the patient's consent, permission from the hospital authorities, private physicians and subject's relatives are obtained. The nature and need of procedures and the purpose of the study were explained to the patients during the initial stage. Aerobic exercises given for each individual subjects administered with the proposed variables like squat thrust, pushups, rope skipping, bench stepper, sit ups, and dumbbell exercise for 1 hour continuously for 3 days in a week for 8 consecutive weeks. The amount and types of physical activity given was as proposed by Canadian Diabetes Association in 2003, with frequency at least 3 days/week, intensity - moderate or intense, duration/mode accumulate at least 150 minutes per week and resistive training frequency of 3 days per week with initially 1 set of 10 – 15 repetition and progression to 3 sets of 8 - 12 repetition. Pre exercise assessment was taken. First laboratory test including fasting blood glucose level and cardiac evaluation was done by checking resting heart rate. Blood glucose level is taken on 1st day, 30th day and the 60th day. Resting heart rate measurements are taken at the beginning and at the end of the exercise. Resting heart rate was measured by taking radial pulse for 1 minute in sitting.

Procedure of aerobic exercise program

The exercise program consists of warm up, circuit training and cool down components. A 10 minutes pre exercise warm up exercise such as mild jogging and stretching exercise was incorporated. Instruction cards are displayed at each station indicating the number of repetitions for each exercise.

Procedure for squat thrust

The subjects adopted as starting position of squatting with legs apart and hands resting on each side of the floor for balance. The action performed was jumping with legs apart in mid air and squat landing with legs apart.

Procedure for pushups

Pushups were performed with the body inclined and supported by hands and feet, shoulders flexed to 90 degree and elbow straight. Subjects will lower their body by flexing the elbows to about 90 degree and then push up.

Procedure for sit ups

Sit up were performed in pairs of two, with one adopting a crook lying position on the floor or mat and the other stabilizing the leg. Subject folded both arm across their chest and lifted the upper body off the floor until it made an angle of approximate 60 degree.

Procedure for rope skipping

Rope skipping were performed with simple skipping rope and subjects skipped at the rate of 90 times per minute with alternate feet.

Procedure for bench stepper

Bench stepping were performed with a 7 ½ inches height stepper with one leg up and come down with other leg alternatively.

Procedure for upper limb exercise

Upper limb exercises were performed in standing with shoulders in anatomical position, elbows fully flexed and each hand holding a dumbbell. Subjects elevated the dumbbells maximally on alternate sides in a rhythmically manner. Afterwards the subjects exercise the biceps by rhythmically lowering and lifting the dumbbells with elbow extension and flexion. Then a 10 minutes post exercise cool down of low intensity exercise such as jogging and stretching exercise was incorporated to prevent musculo- skeletal injuries.

RESULTS

Both the groups were analyzed by using Fasting Blood Glucose levels. The data was analyzed using the paired t- test and unpaired t-test. The results were measured according to fasting blood glucose level. None of the patients underwent any kind of complication during the study. Data analysis was done using statistical methods.

Table 1. Comparison of Conventional Oral Therapy Medication Group and Exercise & Diet Group

Group Statistics

	GROUP	N	Mean	Std. Deviation	t
DAY1	Conventional Oral therapy	20	125.2000	4.42005	6.33200
	Exercising & diet	20	140.8000	10.09221	p=.001 vhs
DAY30	Conventional Oral therapy	20	126.1000	4.89791	4.41700
	Exercising & diet	20	137.2500	10.17155	p=.001 vhs
DAY60	Conventional Oral therapy	20	125.8500	4.78237	3.44300
	Exercising & diet	20	134.4500	10.09677	p=.001 vhs

In the above table comparison is being done between Conventional oral therapy group and exercise and diet group before starting the

Paired Samples Test

		Paired Differences				
GROUP		Mean	Std. Deviation	t	р	
Conventional Oral therapy	DAY1 - DAY30	9000	3.90546	-1.031	_	.316
	DAY1 - DAY60	6500	3.37600	861		400
	DAY30 - DAY60	.2500	1.55174	.721		480
Exercising & diet	DAY1 - DAY30	3.5500	1.39454	11.384	.001 vhs	
	DAY1 - DAY60	6.3500	1.92696	14.737	.001 vhs	
	DAY30 - DAY60	2.8000	1.15166	10.873	.001 vhs	

treatment i.e. 1st day. The number of patients in both groups was 20. The mean Fasting blood glucose level for conventional oral therapy group is 125.2000 and for exercise and diet group it is 140.800. The standard deviation was 4.42005 and 10.09221 for conventional oral therapy and exercise and diet groups respectively. After 30 days of treatment the mean fasting glucose level for conventional oral therapy was 126.1000 with standard deviation of 4.89791. In the exercise and diet group, the corresponding mean fasting blood glucose level is 137.2500 with standard deviation of 10.17155. After 60 days of treatment the mean FBG level for conventional oral therapy group was 125.8500 with S.D of 4.78237. In the case of exercise and diet group the mean FBG level is 134.4500 with S.D of 10.09677. The paired difference is indicated in the above table for both conventional oral therapy group and exercise and diet group. The paired difference for mean FBG level in conventional oral therapy group from day 1 to 30 th is -.9000 with S.D of 3.90546. For day 1 to 60th mean FBG level is -.6500 with S.D of 3.37600 and mean FBG for day 30 to 60th is .2500 with S.D of 1.55174. The result showed that there was no significant from day 1 to 60th. Whereas the paired difference for mean FBG level in exercise and diet group for day 1 to 30th is 3.5500 with S.D of 1.39454. For day 1 to 60th mean FBG level is 6.3500 with S.D of 1.92696 and FBG level for day 30 to 60th is 2.8000 with S.D of 1.15166. The result shows that there is reduction in FBG level, which is very highly significant from day 1 to 60th. (0.001).

Group Statistics

	GROUP	N	Mean	Std. Deviation	t
DIF130	Conventional Oral therap	20	9000	3.90546	4.77900
	Exercising & diet	20	3.5500	1.39454	p=.001 vhs
DIF160	Conventional Oral therap	20	6500	3.37600	8.05300
	Exercising & diet	20	6.3500	1.92696	p=.001 vhs

The above table indicates the mean reduction in FBG level between Conventional oral therapy group and Exercise and diet group. The mean difference FBG level for Conventional oral therapy group from day 1 to 30^{th} is -.9000 with S.D of 3.90546 and for exercise and diet mean difference from day 1 to 30^{th} is 3.5500 with S.D of 1.39454. Again the mean difference level for Conventional oral therapy group from day 1 to 60^{th} is -.6500 with S.D of 3.37600 and for Exercise and diet group mean difference from day 1 to 60^{th} are 6.3500 with S.D of 1.92696. When both groups are compared, the exercise and diet group shows very highly significant reduction in FBG levels as compared with Conventional oral therapy group. (p = 0.001).

DISCUSSION

The present study examined the influence of Circuit training, a novel exercise prescription involving aerobic and resistance modalities, in subjects with type 2 diabetes. The rationale behind this combined method of training was that aerobic exercise and diet together improves lifestyle, improves muscle mass, strength and shows improved insulin sensitivity. The principle findings of this study were that circuit training showed improvement in decreasing fasting blood glucose level in NIDDM patients. Recent studies suggests that training programs which involve resistive exercise component, that is moderate intensity weight lifting exercise, may be of particular benefit in type 2 diabetes, due to an effect of increased insulin action. ⁸ Increase in muscle mass has been associated with benefits in terms of glycemic control⁸ as skeletal muscle represents the largest mass of insulin sensitive tissue. Circuit training was also associated with increased aerobic capacity, which enhanced glucose uptake possibly due to increased blood flow and enhanced tissue exposure to insulin and glucose. In the present study, it showed that H.R decreased following training. These findings indicate that aerobic capacity increases following circuit training, a result of clinical importance as studies indicate that physical inactivity is associated with glucose intolerance. One more finding of the present study was that exercise programs consisting of a training duration of 170 min/wk, regardless of variations in exercise intensity (range, 40–80% $\dot{V}{\rm O}_{\rm 2\,peak}$) and

weekly training volume, improved insulin sensitivity to a similar degree. Our findings thus suggest that, within the exercise training paradigms used in the present study, exercise duration is one of the primary factors that control the response of insulin action to exercise training. The conclusion is that weekly exercise duration appeared to be an important variable influencing change in insulin sensitivity.

Improved glycemic control may be associated with the cumulative effect of frequent high intensity acute exercise that results in lowering blood glucose levels (Koivisto, Yki-Jarvinen, and DeFronzo, 1986; Schneider et al., 1984)⁹ and improvements may be seen within a week of beginning intense exercise (Rogers et al., 1988). Exercise training for patients with NIDDM has not always improved glucose tolerance and plasma insulin levels (Ruderman et al., 1979; Saltin et al., 1979; Schneider et al., 1984; Trovati et al., 1984). Huh et al., in his study reported that exercise training over a period of 14 weeks to 34 weeks was ineffective in improving fasting plasma levels or oral glucose tolerance in middle aged, moderately obese subjects with NIDDM. These authors found that exercise training without weight loss was ineffective in reducing fasting glucose, insulin, and lipid levels and for improving oral glucose tolerance in subjects with NIDDM. To be most effective, exercise training may need a calorie restricted diet. Our data thus agrees with some of the other studies that relatively moderate-intensity physical activity can enhance insulin sensitivity, which is a relevant finding in relation to clinical recommendations for intervention/prevention. Improved blood glucose levels through physical training alone or in combination with diet have been demonstrated in young and middle aged individuals with type 2 diabetes. (Bogardus et al., 1984; Krotkiewski et al., 1985) 10 Improved glycemic control trough exercise training that improves VO2 max is best accomplished in individuals with mild type 2 diabetes who are hyperinsulinemia but have FBG levels less than 200mb/dl (Rogers et al., 1988; Ronnemaa et al., 1986; Schneider et al., 1984; Trovati et al., 1984). The major implication of this finding is that these patients secrete more insulin than people with severe hyperglycemia and that hyperinsulinemia is reduced with exercise training. (Holloszy et al., 1986; Rogers et al., 1988).

The clinical significance of this study is that exercise program is simple and does not require any sophisticated equipment. These exercises can be easily incorporated with people of type 2 diabetes. More, importantly, for type 2 diabetic patients who have a relatively sedentary lifestyle, the present study shows that their insulin sensitivity improved with only 30 days of exercise thrice a week at moderate intensity. Mild exercise training increases insulin action despite no influence on maximum O2 uptake. Along with evident benefits in health promotion, moderate intensity exercise plays an important role in facilitating treatment of type 2 diabetes. Krishna V Bhaskabhatla states that exercise for 30 min or more at moderate level of intensity can improve insulin sensitivity and glycemic control and decrease the need for oral medication or insulin. 11 Studies on the effects of resistance training in type 2 diabetes are not available, although one study found that aerobic and resistance training had similar effects on insulin action. This suggests that improvements in insulin action from exercise training can occur without concurrent improvements in cardio respiratory fitness. This evidence is bolstered by results from short term exercise training interventions in which no improvements in cardio respiratory fitness were observed.

Conclusion

- Diet and/or exercise interventions led to a very highly significant decrease in the fasting blood glucose levels among those with NIDDM.
- There was a significant change in the lifestyle measures of people with NIDDM after starting exercise program.
- Diet and exercise intervention were beneficial and effective with NIDDM patients as compared with conventional oral therapy medications.

In conclusion, we have found sufficient evidences that support the theory that combined with other forms of therapy, mild exercise training increases insulin action. Along with evident benefits in health promotion, moderate-intensity exercise plays an important role in facilitating treatment of NIDDM. Thus this study matches with the hypothesis that aerobic exercise and diet together is beneficial and effective as compared with conventional oral therapy with NIDDM patients.

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