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New Intervention Protocol for Training Cardiorespiratory Endurance Among Type 2 Diabetes Mellitus Patients with Poor Glycemic Control – An Experimental Study

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Abstract

Background and Purpose – Poor glycemic control among diabetic patients poses a great challenge for a physiotherapist in prescribing exercises. To develop a regimen for hyperglycemic patients to train cardiorespiratory endurance. **Methodology** – in this quasi-experimental study subjects between 30 to 60 years of age with type 2 Diabetic Mellitus (T2DM) were randomized into three groups namely Group A (not supervised and regularly monitored physiotherapy) Group B (aerobic exercise training with a frequency of at least 3 days/week performed at least at moderate intensity, which is approximately 40–60% of VO2max) and Group C (received a newly framed protocol). **Results –** there was a baseline homogeneity in all the demographic data and the pre-test values of the three groups. Further, the results showed that there was a significant improvement in group C compared to group A and B. **Conclusion -** we suggest the newly framed Madhav university exercise protocol for the hyperglycemic patients with type 2 diabetes Mellitus for improvement in perceived exertion rate, endurance, agility and quality of life.

Keywords: Type 2 Diabetic Mellitus, Physiotherapy, Cardiorespiratory endurance.

1. INTRODUCTION:

Physical function of the body focuses on developing cardiorespiratory fitness is directed as part of the quality of care treatment for Type 2 Diabetes by the American Diabetes Association, in the year 2011, primarily because irregular managed clinical tests show that the exercise training decreases hyperglycemia in individuals with Type 2 Diabetes by Karstoft, et al, in 2013 and suspends the beginning of Type 2 Diabetes at a threat for the peoples by Pan XR, et al, in 1997. Interestingly, in a long-term analysis of 8,633 nondiabetic men, Blair and colleagues viewed greater cardiorespiratory fitness as decided by increased oxygen consumption, measured during exhaustive incremental workload exercise activity consults defense against developing Type 2 Diabetes-related hyperglycemia by Wei M et al, in 1999. A further long-term analysis by Church et al, examining 2,316 men with Type 2 Diabetes, stated that greater cardiorespiratory fitness decreased cardiovascular disease death. Consequently, bad fitness is regarded as a key aspect of the pathophysiological development of glucose intolerance.

However, because the weak glucose constitution, driven by insufficient β-cell insulin activity in the presence of weak insulin sensitivity, is the actual basic reason for hyperglycemia in Type 2 Diabetes, it is diplomatic to decide whether the cardiorespiratory fitness is interrelated to those pathophysiological factors. The aerobic exercise activity training that upgrades the cardiorespiratory fitness also rises the insulin sensitivity by Kirwan JP et al, in 2009 and thus upgrades the β-cell insulin activity by Solomon, et al, in 2010 in individuals with Type 2 Diabetes. However, the indicative value rate of cardiorespiratory fitness for deciding the longitudinal glycemic control is well stated by an association between the fitness and the fundamental factors of glycemic control are insulin sensitivity or insulin activity secretory function is unclear. With several facts and beliefs regarding T2DM management, the exercise provided should be tailored to the individual. The exercises that are conducted should be precise, as well as effective. This demonstrates the importance of developing a therapy list that is tailored to the target demographic. To our knowledge, there is no protocol for the exercise treatment of hyperglycemic patients training cardiorespiratory endurance. As a result, this study will adopt an honest approach to developing a regimen for hyperglycemic patients to train cardiorespiratory endurance.

2. METHODS:

A quasi-experimental study with simple random sampling was conducted in a rehabilitation center, physiotherapy outpatient Department, and Faculty of physiotherapy. The study was approved by the institutional ethical committee of Madhav university and was cleared for any human ethical issues. (Ethical certificate–MU/IEC/20/07).

Subjects between 30 to 60 years of age with the presence of type 2 Diabetic Mellitus which should be tested by an ISO certified laboratory within a duration of ten days maximum, both male and female are included, Subjects under insulin therapy, oral hypoglycaemic agents with no systematic/musculoskeletal red flag, able to understand the purpose of the study (English or Hindi) which will be explained by researcher and willingness to participate in the study were considered for inclusion.subjects with previous history of thoracic and abdominal surgery, chronic Smokers (minimum 10 Pack years) and Alcoholics, congenital heart disease or Ischemic Heart Diseases, obstructive and restrictive lung disease, systemic hypertension, peripheral vascular diseases , Obesity with BMI more than 34,TB, Asthma, Hepatic and Renal diseases, Endocrine disorders other than diabetes, hemoglobin less than 12gm%, any other conditions that may affect the relationship between the dependent and the independent variable and act as a confounding variable were excluded.

Subjects who met the inclusion criteria were recruited for the study and all the subjects participating in the study were explained clearly about the study and signed an informed consent form. Subjects who are enrolled in the study will be undergoing a standardized assessment which includes demographic and medical information such as age, sex, ethnicity, alcohol, and history of smoking, all anthropometric measurements were taken using calibrated equipment, and also Blood glucose levels should be noted too. Before going for evaluation, subjects Will be randomly allocated to three different groups using a simple random sampling method. Each group will be assigned to different treatment protocols group A (placebo), group B (control group), and group C (experimental group). Based on the established protocol which is assigned for each group will be followed to determine the effect of the newly framed intervention protocol on cardiorespiratory endurance among type 2 Diabetes mellitus patients.

Intervention

Group A –The subjects in this group were receiving oral hypoglycaemic agents, with a strict diet pattern prescribed by a dietician which was tailor-made with a fixed proportion of carbohydrates and with minor variations in the protein, and fat intake. Apart from this the subjects also performed exercises for 40 minutes a day based on their interest but it was not supervised and regularly monitored by a physiotherapist. The subject followed various exercise regimens of their will and followed the various school of exercise whereas few subjects followed the YouTube videos. This routine was followed for 5 days a week, for 8 consecutive weeks with one treatment session per day.

Group B- They received aerobic exercise training with a frequency of at least 3 days/week but not more than two consecutive days between the aerobic bouts of activity due to the transient nature of exercise-induced enhancement in insulin action**.** The exercises were performed at least at moderate intensity, which is approximately 40–60% of VO_{2max} (maximal aerobic capacity). For example, brisk walking is a moderate-intensity exercise. Apart from brisk walking all other exercises that use a large group of muscles and cause sustained increases in HR were included in the study. The subjects engaged in a minimum of 150 min/week of exercise to a maximum of 200 min/week.

Resistance exercise training was also advised with a frequency of twice weekly on non-consecutive days with moderate intensity (50% of 1-repetition maximum [1-RM]) which was aimed at optimal gains in strength and insulin action. Home-based resistance training or gym-based training was suggested using dumbbells, barbells, and medicine balls. Each training session lasted for 40 minutes with 10-15 repetitions to near fatigue per set early in training. It comprises 5–10 exercises involving the major muscle groups namely the trapezius, deltoid, Biceps, Triceps, hamstrings, quadriceps, calf, and abdominals. hydraulic, pneumatic exercise machines and free weights (like dumbbells and barbells) were used.

Group C received a newly framed protocol with the following principals

A. Selection of exercises based on the individual's interest from a combination of aerobic exercises and anaerobic exercises, agility training, and most importantly functional exercises that mimicked the actual life activity like squats, lunges, sit to stand, staircase climbing, floor sitting, and so on.

B. Circuit training that emphasized both aerobic and anaerobic demands was used.

C. Group activities comprising at least 4 subjects to 8 subjects were used on at least two days of the week.

D. Exercises were performed in anticipation to give a variety of activities that were possible in the patient's domestic ambiance rather than in a gym.

E. walking as an exercise was advised only twice a day with at least 2 days in-between two consecutive sessions.

F. At least one vigorous exercise (>60% of Vo2max) aerobic session per week was advised in the form of treadmill running or elliptical or jogging for 12 minutes to 20 minutes.

Outcome measures :

VO2 Max - VO2 max is an analysis of the maximum amount of oxygen that a person consumes during intense physical activity. Vo2 max is the best indicator of aerobic endurance, as well as cardiovascular fitness as it calculates how efficiently human cells use oxygen in generating energy. We employed a walking/jogging test though they are many methods for measuring VO2 max, however many methods require equipment like a treadmill or an exclusively calibrated exercise cycle. But it has many difficulties to administer and is not feasible for all fitness levels. The patient's maximum heart rate was calculated by subtracting the patient's age from 220.

VO2 max = 15 x (Heart rate/Heart rate rest). The units for VO2 max are milliliter per / body weight in kilograms / minute (mL/kg/min).

"T" Agility test - Subjects were requested to run straight for 9.14 m from the beginning line to the primary cone and contact the tip with their right hand, then shuffle for 4.57 M from the left to the subsequent cone and contact with their left hand, then, at that point, again shuffle for 9.14 M to the right to the third cone and contact with their right, shuffle 4.57 m back left to the center cone and contact with their left hand before at last returning to the beginning line. Time started upon subjects elapsing through the circumstance entryways and halted upon them going through on return. (Figure 4.3). The test won't be counted if the subject crosses one step at a time while rearranging, neglects to contact the foundation of the cones, or neglects to look ahead all through the test. Take the best season of three fruitful preliminaries. [Allan et al, 2011]

Sample size: It is determined using G power software version 3.1.9.7. the results are displayed below and in figure 5.1 and table 5.1. The sample size arrived at 99 with an effect size of 0.18. This means 33 samples per group and this was inflated by 10 % to account for the dropouts and arrived at 37 per group which means a total of 111 overall samples.

Randomization - Though a convenient sample was used to select the sample from the population, a random table method was used as the method used to generate the random allocation sequence. A physiotherapist who was not concerned about the study, with a minimum of 5 years of clinical experience, was used for random allocation, who generated the random allocation sequence, enrolled participants, and assigned participants to interventions.

Blinding - The assessor who was not part of the study intervention delivery, was blinded to assignment to interventions, and was employed for testing the outcome measures.

Statistical analysis

The study used SPSS software version 26, with a confidence interval of 95% with a significance level of 0.05. Chi-square analysis was used for analysing the baseline homogeneity for analyzing the demographic data. Between groups, analysis was performed for paramedic data using ANOVA, and non-parametric data using Kruskal–Wallis one-way analysis of variance. Within-group, analysis was performed using repeated-measures ANOVA for parametric data and the Friedman test was used for non-parametric data.

3. Results:

The demographic data were analyzed for homogeneity. The basic criteria like age, height, weight, BMI, educational standards, lifestyle, and employment status. The analysis of age was categorized into 36-40 and 41-45 years. There were no statistical differences between the groups in age distribution with a Chi-square value of 0.216 and a p-value of 0.897. The analysis of height was categorized into 146.1-155, 155.1-165 and165 –above in cms. There were no statistical differences between the groups in height distribution with a Chi-square value of 0.329 and a p-value of 0.987. The analysis of weight was categorized into “50.1-60”, “60.1-70”, “70.1-80”, and “80.1- above” in cms. There were no statistical differences between the groups in weight distribution with a Chi-square value of 0.307 and a p-value of 0.999. The analysis of BMI was categorized into 18.5-24.9, 25-29.9, and 30 - above. There were no statistical differences between the groups in BMI distribution with a Chi-square value of 0.307 and a p-value of 0.999. The analysis of educational standards was categorized into Till 8 the standard, 8 the standard till plus 2 and graduate. There were no statistical differences between the groups in educational standards distribution with a Chi-square value of 0.182 and a p-value of 0.996. The analysis of lifestyle was categorized into sedentary and active. There were no statistical differences between the groups with a Chi-square value of 0.072 and a p-value of 0.965. The analysis of employment was categorized into employed and unemployed. There were no statistical differences between the groups with a Chi-square value of 0.075 and a p-value of 0.963.

4. Discussion

This study was performed with the primary aim to find the influence of glycemic control on cardiorespiratory endurance among the community-dwelling Diabetic (type 2) subjects. The primary objective was to find the correlation between glycemic control and cardio-respiratory endurance among community-dwelling hyperglycemic subjects and to find the correlation between glycemic control and various factors of fitness namely quality of life, endurance, and agility among community-dwelling hyperglycemic subjects. Phase 1 of the study hypothesized that there is no correlation between glycemic control and cardio-respiratory endurance (Vo2 max) among community-dwelling hyperglycemic subjects. Phase 2 of the study hypothesizes that there is no correlation between glycemic control and various factors of fitness namely perceived exertion rate, endurance, agility, and quality of life among community-dwelling hyperglycemic subjects.

Research on the western population suggests an inverse relationship between cardiorespiratory fitness and the likelihood of developing diabetes. This indicates that diabetes has a significant impact on an individual's ability to exercise, lowering one's quality of life. Exercise is one of the preferred glycemic control strategies for people with Type 2 diabetes. Diabetes mellitus is a disorder of carbohydrate, lipid, and protein metabolism characterized by a decrease in tissue insulin sensitivity or a lack of insulin production. Increased non-enzymatic glycosylation of numerous bodily proteins such as hemoglobin, collagen, and albumin occurs as a result of persistent hyperglycemia. The Glycemic index is calculated by measuring the levels of glycated hemoglobin (Hb1Ac). Glycation occurs during the red blood cell's lifetime (90-120 days). HbA1c is the average blood glucose levels during the previous 3-4 months. A high Hb1Ac level suggests poor blood glucose control or a high Glycemic index. There is a wealth of material accessible in western literature, which brought into account western sedentary lifestyle habits. However, there is a scarcity of information on Indian Diabetics.

The mean value of HbA1c in our study was 7.8 ± 0.74 %. It was observed that the subjects treated using OHA had higher GlycatedHemoglobin levels than the subjects treated with Insulin therapy. This suggests that the Diabetics' diabetes was poorly managed among the subjects who took OHA. The higher the level of GlycatedHemoglobin, the poorer the control of blood sugar i.e. higher is the level of circulating glucose, and as discussed earlier hyperglycemia leads to non-enzymatic glycation of intracellular and extracellular proteins forming advanced glycation end products (AGEs).

Maximal Oxygen Consumption (VO2max) - mean Resting pulse rate, Post-Exercise pulse rate & VO2max level in Type 2 Diabetics were 75.7 ± 6.12 beats/min, 149.04 ± 6.8 beats/min, 2.69 ± 0.308 L/Min. The difference in Resting pulse rate was nonsignificant, While, Post-Exercise pulse rate was significantly higher in subjects with higher HbA1C than in subjects who had less HbA1C. When Type-2 Diabetics were compared to controls, their VO2max was considerably lower. Schneider H. et al came to similar conclusions in 2008. This could be accounted for by an increased Glycolytic to Oxidative enzyme ratio, which is induced by increased Glycolytic enzyme activity combined with a decrease in the maximum speed of Oxidative enzymes. i.e citrate synthase & Cytochrome-c oxidase contributes to Insulin resistance in subjects with Type-2 Diabetes. Dysfunction in GLUT4 translocation owing to either signal transduction or intrinsic to the glucose transporter mechanism has been proposed as the primary cause of insulin resistance. Also, decrease in the enzymatic activity regulating storage and oxidation of glucose in skeletal muscle. Muscle fiber type and composition found in studies with diabetes such as changed skeletal muscle fiber type as well as increased fat content, capillary basement membrane width in the skeletal muscle may result in low work efficiency. The accumulation of Intramyocellular Triglycerides (IMCL). which correlates well within Vivo Insulin Resistance. In particular, the major issue generating IMTG (Intramyocellular Triglycerides) buildup and muscle insulin resistance in obese individuals, IRS, and type 2 diabetes is a failure in muscle fatty acid oxidation. Insulin sensitivity and VO2max are closely associated with a mitochondrial oxidative capability. It is also proposed that, even though the mitochondrial function is regular in type 2 diabetes, connected and disconnected respiration is slowed in type 2 diabetic individuals, resulting in decreased mitochondrial content. There is also an increased incidence of mitochondrial DNA abnormalities in skeletal muscle of Type-2 diabetic patients, with one deletion, in particular, 4,977 bp, being found to be considerably enhanced in Type-2 Diabetes Mellitus or impaired glucose tolerance muscle tissue. It is demonstrated that insulin-induced Mitochondrial ATP production is also compromised in Type-2 Diabetes. Factors leading to the development of the decreased glucose transport capacity mediated via insulin in skeletal muscle, are attributed to be included reduced blood flow and elevated free fatty acids. It was found that in the hexosamine biosynthetic pathway there was an increased routing of glucose which could be a contributing factor to the development of the muscle insulin resistance in Type-2 diabetes. Also Defronzo RA.(1992) (38), Reaven G. (1988) in middle-aged Type-2 Diabetics, despite fasting Hyperinsulinemia, have increased basal hepatic glucose output, impaired glycemia induced insulin release & increased resistance to Glucose disposal mediated by insulin actions. Similar results were also observed by Meneilly GS. et al. in 1999. Thus poor glucose control (Hyperglycemia) may influence VO2max, i.e. the Cardio-Respiratory fitness.

Phase 2 of the study was the continuation of phase I as patients who were screened positive from phase 1 were selected for phase 2. This phase was conducted as a non-randomized controlled trial. The samples selected for the study were divided into three groups using a random allocation using the random table method in a 1:1:1 ratio. All the subjects participating in the study were explained clearly about the study and signed an informed consent form. The study was presented to the institutional ethical committee of Madhav university and was cleared for any human ethical issues. The recruited subjects were screened for Cardiorespiratory endurance, Agility, Quality of life, and Blood glucose levels. Vo2 Max, “T” Test, DM QOL, and HBA1C were used as the outcome tool.

As this is a long study period, we expected dropouts so we inflated the sample size by 10% to account for the dropouts. The groups were stratified in terms of baseline demographic data as the groups were similar in age, height, weight, BMI, educational qualification, lifestyle, and employment status. To further clarify the equality of the group the between-group analysis clearly stated that the groups were similar before the intervention. The pre-test values of the three groups for agility testing were very similar and any changes that had happened in the variables should be attributed to the intervention. There was a superior effect in subjects treated with group C intervention in the post-test 1 and as well as post-test 2. However, there was not much difference in the improvement gained through groups A and B. There were similar results in the other outcome measures as well which indicates that the newly framed protocol is best suited for treating the target population. As the author has applied for copyright the full details of the protocol are not furnished here which was intimated and duly permitted by the research supervisor.

The study results were similar to previous results which had shown a significant improvement in agility using exercises among elderly and diabetic patients. A KH in 2015 proved that circuit-type resistance training will have nearly comparable efficacy on weight reduction, body composition, glycemic level, and improvement of insulin sensitivity in non-subjects with type 2diabetic patients. Due to the reduction of weight the patients reported that they were able to do all the agility tasks effectively. Vo2 max had been the vital component that showed a significant improvement with both group B and C intervention however group C showed a superior improvement. In the past literature also there was much research that had been documented in favor of our results. (Oshida et al, 1989, Gormley, et al, 2008 and Karadkhedkar et al, 2015)

5. Conclusion

The results clearly state that all the three groups showed improvement in all the outcome measures and which is the evidence of the impact of any exercises on the human system. However, groups B and C showed a better improvement than group A which is self-performed and non-supervised. This proves that a physiotherapist’s supervision will always enhance the performance of the patients. Among the two groups, the newly framed exercise showed a significantly better improvement than the other groups both in better time and better effect. Thus from this study, we suggest the newly framed Madhav university exercise protocol for the hyperglycemic patients with type 2 diabetes Mellitus for improvement in perceived exertion rate, endurance, agility, and quality of life.

6. References

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