DOI: 10.7860/JCDR/2023/57942.17753

Research Protocol

Physiotherapy Section

Efficacy of Arm Ergometer Exercise on Glycaemic Control in Type 2 Diabetes Mellitus- An Interventional Study

SHUBHADA RAVINDRA DHAIT[1], VISHNU VARDHAN[2], RASHMI WALKE[3]

ABSTRACT

Introduction: Type-2 diabetes develops when the body's natural metabolism is disrupted, which is marked by a decline in glucose tolerance over time. Diabetes mellitus is a dreadful condition specified by an increase in the concentration of glucose that influences the cardiovascular system, veins, arteries, vision, renal system, and ganglion over time. Arm ergometer is an upper body exercise apparatus that quantifies and standardises physical activity in terms of work output. Thus, it is well recognised as an essential component in the treatment of Type 2 Diabetes Mellitus (T2DM).

Need of the study: Exercise has been demonstrated to aid glycaemic management in those at high risk of diabetes. The symptoms of peripheral artery disease, peripheral neuropathy, vision disturbances, renal disease, heart disease, cognitive impairment, and metabolic dysfunction are likely to worsen due to poor glycaemic control. Limited evidences on arm ergometer have shown its effectiveness on glycaemic control.

Aim: To find the efficacy of arm ergometer exercise on glycaemic control in patients with T2DM.

Materials and Methods: This interventional study will be conducted in the Diabetes Out Patient Department (OPD) of Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha, Maharashtra, India from April 2022 to March 2023 after obtaining the ethical clearance. A total of 40 participants with T2DM will be recruited, and after baseline health parameter assessment like postprandial blood glucose, Haemoglobin A1c (HbA1c), and 6-minute walk test, the participant will perform arm ergometer exercise for 30 minutes for 5 days/week. All the parameters will be assessed again after 6 weeks. Frequency distribution will be calculated using Chi-square and pre and post data will be compared using student's paired t-test.

Expected outcome: Arm ergometer exercise will be effective on glycaemic control in T2DM individual.

Keywords: Aerobic exercise, Insulin resistance, Physical activity

INTRODUCTION

The T2DM is caused by a lack of insulin sensitivity over time. This disease develops when the body's glucose metabolism is disturbed. Insulin resistance is commonly triggered either by insufficiency of insulin secretion or a high protein level, both of which can cause it. Insulin resistance is a phrase used to characterise the illness known as T2DM, which is not dependent upon insulin [1].

The global generality of T2DM among those over the age of 18 years has risen, which are the confirmed cases. T2DM is on the rise all over the world. According to the International Diabetes Federation, millions of people worldwide suffer from diabetes, and the number is expected to rise by 2025 [2]. The number of patients unable to control glucose is expected to double in prevalence by 2025, with over 60 million diabetics, and heart disease will be the leading cause of mortality. In industrialised areas, exercise is often recommended along with dietary intervention to regulate glucose and pressure in the arteries in these patients [3]. Adults who live a physically active lifestyle are less likely to possess high blood sugar, glucose intolerance, or T2DM [4].

Upper body muscles are exercised using an arm cycle ergometer. This is easy to perform the eccentric, repetitive, high-force movements with upper body [5]. Patients with type 2 diabetes can benefit greatly from arm exercise for glucose control [6]. Regular performing arm swing exercise can improve insulin sensitivity and concentration, resulting in a drop in HbA1c level [7]. Physical activity encompasses a wide range of activities such as active living, regular exercises, and the ability to carry oneself [8].

Inadequate secretion of insulin by pancreatic islet cells, tissue's refusal for insulin, and a compensative insulin secretory reaction are all signs of T2DM in more than 90% of patients. Insulin synthesis and release responses at the micro-level are all tightly managed to meet metabolic demand. To summarise, any fault in any of the systems can result in a metabolic imbalance, which can contribute to the development of T2DM [9].

Two weeks of physical training enhances cellular condition and decreases fat in the pancreas within borderline diabetic and T2DM subjects, in any case of their baseline glucose tolerance. Exercising for a short period practically reduces excess fat in the pancreas, revealing that physical activity is beneficial and may control blood sugar levels [10].

Arm ergometer exercise is well-established physical activity and plays a crucial part in the care of diabetic disease [11]. In terms of glucose profile, it is well recognised that daily exercise assists blood glucose control, which is an essential element in the care of T2DM [12]. The study aims to find the efficacy of arm ergometer exercise on glycaemic control in patients with T2DM. Arm ergometer exercise has been proven to be a significant predictor of serum glucose levels [6]. This modality seems suitable for measures of cardiorespiratory fitness [13]. The serum glucose levels are controlled by arm ergometer exercise [6]. Exercises have been demonstrated to aid glycaemic management in those at high risk of diabetes. It is well-established that aerobic exercise training, such as brisk walking and treadmill use, can improve systemic glucose management in people with T2DM [6,12,13] but there are paucity of literature demonstrated effectiveness of upper extremity endurance exercise in regulating blood glucose level in patients with T2DM.

The null hypothesis of the study suggests that arm ergometer exercise will not have a significant effect on glycaemic control in T2DM. The study hypothesised that arm ergometer exercise has a significant effect on glycaemic control in T2DM.

MATERIALS AND METHODS

Present interventional study will be conducted in the Diabetes OPD of Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha, Maharashtra, India over a period of one year, from April 2022 To March 2023. Study will be conducted, after receiving ethical approval from the Institutional Ethical Committee of Datta Meghe Institute of Medical Sciences- DMIMS(DU)/IEC/2022/902, also study was registered under CTRI India{CTRI Registration Number: CTRI/2022/06/043196}. Principal Investigators will get the participant's written informed permission on a printed form (in their native language) with signatures and verify confidentiality.

Inclusion criteria: Males and females having T2DM, who will sign the consent form, within the age of 30-50 years will be included in the study.

Exclusion criteria: Patients with T2DM, serious psychiatric problems, serious or uncontrolled complications of DM, critically ill patients, and with inflammatory diseases, including acute and chronic cardiac conditions, pregnancy, smoking, drug and alcohol abuse, and musculoskeletal disorders will be excluded from the study.

Sample size calculation: It was calculated by taking the prevalence of T2DM as 2.25% from previous study [12]. With the level of significance at 5% i.e., 95% confidence interval and desired error of margin 6%. Daniel formula as given below was used and 39 was the sample size was rounded off to 40. Therefore, 40 participant will be recruited in the study (n=40).

$$n=\frac{Z^2_{\frac{a}{2}} . P . (1-P)}{d^2}$$

Where, $Z^2_{\frac{a}{2}}$

is the level of significance at 5%

i.e., 95% confidence level

P=Prevalance of diabetes mellitus in subjects <50 years=2.25%=0.025

D=Desired error of margin=6%=0.6

$$n=\frac{(1.960)^2\times0.038\times(1-0.038)}{(0.06)^2}$$

=39.00

n=40 patients in each group

Patients who visited physiotherapy diabetes OPD in Acharya Vinoba Bhave Rural Hospital with complaints of an increase in the blood glucose level and who fulfilled the inclusion criteria will be recruited.

Outcome Measures

Primary outcome measures

- Postprandial blood glucose level: Blood glucose monitoring will be used to track variations in glucose levels as a result of food, exercise, or other diabetes-related conditions.
- HbA1c: The percentage of glucose molecules that mix with haemoglobin to form glycated haemoglobin will be analysed by this test, which remains for around 60-120 days (life of RBC). More than 6.5% confirm that person has diabetes. This will be evaluated on day 1 and on the last day of the 6th week [14].

Secondary outcome measures

- 6 minute walk test: Cardiorespiratory fitness will be measured with this test. This assess the efficacy of various therapeutic strategies and determines the prognosis of individual with heart disorders. The pre and post vitals (oxygen saturation, respiratory rate, heart rate and blood pressure) will be monitored. The score will be interpreted through the 30 minute walk distance covered by the patient in 6 minutes [15].

Participant timeline: The treatment will last for six weeks. So each patient will be expected to complete 6 weeks of treatment after enrolling in the research. The assessment will be done on 1st day of the visit and then at the last day of 6th week.

Study Procedure

After receiving approval from the ethical committee, a proper explanation of the technique will be given to the participants. All those who will be signing the consent form will be included in the study. The patients details such as heart rate, respiratory rate, blood pressure, oxygen saturation will be recorded, and baseline outcome measures will, be obtained. A glucometer (Dr. Morepen BG-03 Gluco one glucometer) will be used for the pre and post exercise to check blood glucose levels. The method will include wiping the area with an alcohol prep pad, piercing the fingertip, and then using cotton to blot the site. The readings will be taken by inserting the strip into the glucometer.

The increased heart rate has been linked to both hyperinsulinaemia and elevated blood glucose levels. Thus, maximum heart rate will be calculated using 220-Age formula [16]. Target heart rate will be calculated using Karvonen formula [17]. The interventions will be followed as mentioned below and assessed with the same outcomes. The vitals of the patients will be monitored throughout the training session through pulse oximeter.

The complete assessment and evaluation of the patients will be done on day 1, as mentioned in the precase record form, and on the last day of the 6th week. The exercise training program will be prescribed based on American College of Sports Medicine (ACSM) Frequency, Intensity, Type and Time (FITT) principle for diabetes mellitus [18]. The patients will be receiving the arm ergometer exercise (Brand: Healthcave, 4.5 kg, 38.1×10.2×27.9, ABS plastic, alloy steel).

The patient will sit comfortably on a chair with an arm ergometer on the table. The total duration of the study will be 30 minutes including 5 minutes of warm up and 5 minutes of cool down exercise. Frequency will be 5 times/week for 6 weeks. Intensity will be 40%-60% of heart rate reserve. Time will be 30 minutes. Type will be aerobic exercise (upper arm ergometer) [19].

STATISTICAL ANALYSIS

The latest version of Statistical Package for Social Sciences (SPSS) will be used to perform statistical analysis. The Chi-square test of independence will be used to access baseline characteristics. The descriptive and interferential statistics will be done using Student t-test to evaluate pre and post data. The statistical test will be conducted with a confidence interval of 95% to evaluate the effect of pre and postintervention.

REFERENCES

[1] Motahari-Tabari N, Ahmad Shirvani M, Shirzad-E-Ahoodashty M, Yousefi-Abdolmaleki E, Teimourzadeh M. The effect of 8 weeks aerobic exercise on insulin resistance in type 2 diabetes: A randomised clinical trial. Glob J Health Sci. 2014;7:115-21.

[2] Tabish SA. Is diabetes becoming the biggest epidemic of the twenty-first century? Int J Health Sci (Qassim). 2007;1:V-VIII.

[3] Jeon CY, Lokken RP, Hu FB, van Dam RM. Physical activity of moderate intensity and risk of type 2 diabetes: A systematic review. Diabetes Care. 2007;30:744-52.

[4] Kirwan JP, Sacks J, Nieuwoudt S. The essential role of exercise in the management of type 2 diabetes. Cleve Clin J Med. 2017;84:S15-21.

[5] Elmer S, Danvind J, Holmberg HC. Development of a novel eccentric arm cycle ergometer for training the upper body. Medicine and Science in Sports and Exercise. 2012;45(1):206-11.

[6] Jeng C, Chang WY, Chen SR, Tseng IJ. Effects of arm exercise on serum glucose response in type 2 DM patients. J Nurs Res. 2002;10:187-94.

[7] Lochaya S, Phonyiam R, Terathongkum S, Lininger J. Effects of arm swing exercise program on blood sugar level, nutritional status and perceived self-efficacy for exercise in persons with uncontrolled type 2 diabetes mellitus. The Bangkok Medical Journal [Internet]. 2018 [cited 2022 Sep 19];14. Available from: https://scholar.archive.org/work/tb22m5wy7jdztncalku3synwkq.

[8] Dhankar NTS. Correlation of physical activity with fear of fall in patients with total knee replacement- A research protocol. Indian Journal of Forensic Medicine & Toxicology. 2021;15:1835-39.

[9] Galicia-Garcia U, Benito-Vicente A, Jebari S, Larrea-Sebal A, Siddiqi H, Uribe KB, et al. Pathophysiology of type 2 diabetes mellitus. Int J Mol Sci. 2020;21:E6275.

[10] Heiskanen MA, Motiani KK, Mari A, Saunavaara V, Eskelinen JJ, Virtanen KA, et al. Exercise training decreases pancreatic fat content and improves beta cell function regardless of baseline glucose tolerance: A randomised controlled trial. Diabetologia. 2018;61(8):1817-28.
[11] McCarthy M, Yates T, Webb D, Game F, Gray L, Davies MJ. Health impacts of seated arm ergometry training in patients with a diabetic foot ulcer: Protocol for a randomised controlled trial. BMJ Open. 2020;10(6):e039062. Doi: 10.1136/bmjopen-2020-039062. PMID: 32565482; PMCID: PMC7311002.
[12] Deo SS, Zantye A, Mokal R, Mithbawkar S, Rane S, Thakur K. To identify the risk factors for high prevalence of diabetes and impaired glucose tolerance in Indian rural population. International Journal of Diabetes in Developing Countries. 2006;26(1):19-23.
[13] Mitropoulos A, Gumber A, Crank H, Klonizakis M. Validation of an arm crank ergometer test for use in sedentary adults. J Sports Sci Med. 2017;16:558-64.
[14] Abass AE, Musa IR, Rayis DA, Adam I, Gasim I. Glycated hemoglobin and red blood cell indices in non-diabetic pregnant women. Clinics and Practice. 2017;7(4):999.
[15] Beatty AL, Schiller NB, Whooley MA. Six-minute walk test as a prognostic tool in stable coronary heart disease: Data from the heart and soul study. Arch Intern Med. 2012;172:1096-102.
[16] She J, Nakamura H, Makino K, Ohyama Y, Hashimoto H. Selection of suitable maximum-heart-rate formulas for use with Karvonen formula to calculate exercise intensity. Int J Autom Comput. 2015;12:62-69.
[17] Omiya K, Itoh H, Osada N, Kato M, Koike A, Sagara K, et al. Impaired heart rate response during incremental exercise in patients with acute myocardial infarction and after coronary artery bypass grafting: Evaluation of coefficients with Karvonen's formula. Jpn Circ J. 2000;64:851-55.
[18] Colberg SR. Key points from the updated guidelines on exercise and diabetes. Front Endocrinol (Lausanne). 2017;8:33.
[19] ACSMs Guidelines for Exercise Testing and Prescription [Internet]. ACSM_CMS. [cited 2022 Sep 21]. Available from: https://www.acsm.org/education-resources/books/guidelines-exercise-testing-prescription.

PARTICULARS OF CONTRIBUTORS:
1. Resident, Department of Cardiovascular and Respiratory Physiotherapy, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha, Maharashtra, India.
2. Professor and Head, Department of Cardiovascular and Respiratory Physiotherapy, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha, Maharashtra, India.
3. Assistant Professor, Department of Cardiovascular and Respiratory Physiotherapy, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Vishnu Vardhan,
Professor and Head, Department of Cardiovascular and Respiratory Physiotherapy,
Ravi Nair College, Datta Meghe Institute of Medical Sciences,
Wardha-442001 Maharashtra, India.
E-mail: vishnudiwakarpt@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jun 08, 2022
- Manual Googling: Sep 13, 2022
- iThenticate Software: Oct 12, 2022 (20%)

ETYMOLOGY: Author Origin

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. NA

Date of Submission: **May 23, 2022**
Date of Peer Review: **Jun 09, 2022**
Date of Acceptance: **Oct 31, 2022**
Date of Publishing: **Apr 01, 2023**