IMPACT OF PHYSIOTHERAPIST-DESIGNED SUPERVISED EXERCISE PROTOCOL ON MUSCLE STRENGTH, AND AUTONOMIC PARAMETERS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A CLINICAL TRIAL

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ABSTRACT

Background and Objectives: Type 2 diabetes mellitus is a heterogeneous group of disorders characterized by variable degree of insulin resistance, impaired insulin secretion, and increased glucose production. Physical activity is central to the management type 2 diabetes. There is less evidence to suggest the efficacy of combined effect of physiotherapist-designed supervised exercise protocol on muscle strength and autonomic parameters in such subjects. Hence, the present study was designed to evaluate effect of physiotherapist designed supervised exercise protocol of muscle strength and autonomic parameters in this subject population.

Material and Methods: This clinical trial was conducted in thirty (30) adult subjects with type 2 diabetes mellitus including both males and females in the age group of 18 to 65 years. All subjects received physiotherapist designed supervised exercise training protocol consisting of aerobic, resistance & flexibility training. Pre-exercise and post-exercise outcome measurements were taken at baseline, 7th & 14th day in the form of 1-RM for muscle strength and autonomic parameters.

Results: Statistical analysis of outcomes at baseline, 7th day and 14th day showed statistically significant difference in strength (p=0.0001), and reduction in autonomic parameters (p=0.0001)

Conclusion: The therapist designed exercise protocol has shown to improve muscle strength, mean systolic blood pressure, diastolic blood pressure, pulse rate, pulse pressure, mean arterial pressure, rate pressure product. The protocol has also proved to be safe since no adverse event was noted post exercise.

KEYWORDS: Type 2 diabetes mellitus, muscle strength, blood pressure, rate pressure product, aerobic exercise, resistance training, stretching.

INTRODUCTION

The world prevalence of diabetes among adults (aged 20-79 years) was 6.4%, affecting 285 million adults, in 2010, and will increase to 7.7% and 439 million adults by 2030. A national urban diabetes survey performed in six major cities in representative samples of subjects’ > 20 years of age and using WHO criteria showed age-standardized prevalence rates of diabetes and impaired glucose tolerance of 12.1% and 14.0%, respectively [1].

A series of epidemiological studies from Southern India have shown a trend for the increased prevalence of diabetes since 2000.
Recent studies in South India, made an interesting observation of a rapid increase in diabetes with a marked reduction in the prevalence of prediabetic conditions [2]. Crude prevalence of diabetes is 19.5% in the state of Kerala [3]. A high prevalence of diabetes was noted in coastal Karnataka population also [4].

Symptoms in type 2 diabetes mellitus is insidious which includes polyuria, polyphagia and weight loss, hyperglycemia and glycosuria, non-healing ulcers, recurrent respiratory or urinary tract infections, rapid change in refraction of the eyes, steady and unexplained rapid weight loss, unexplained peripheral neuropathy, premature onset of ischemic heart disease, stroke or vascular occlusions [5].

The various complications in type 2 diabetes mellitus patients include cardiovascular diseases, peripheral vascular diseases, neuropathy, nephropathy, retinopathy, decreased in muscular strength, decreased muscle mass, changes in skeletal muscle fibers, decrease in exercise capacity, reduced physical function and mortality that are related to compromised glycaemic control in diabetes, due peripheral neuropathy and reduced vascular supply [6-11]. Other complications include cardiac autonomic neuropathy, a major delayed complication in type 2 diabetes mellitus patients which results from damage to the autonomic nerve fibers that innervate the heart and blood vessels and may result in abnormalities in heart rate control and vascular dynamics [4, 12].

Newly diagnosed diabetic older men have significantly weaker muscle strength and higher odds of impaired physical function than those without diabetes. There is a relationship between raised glucose levels, weaker muscle strength, and impaired physical function [11].

The goal of treatment in type 2 diabetes mellitus is to achieve and maintain optimal blood glucose, lipid, Blood pressure control abnormalities, as well as aid in weight loss and maintenance [13]. Physical therapists are increasingly becoming first line providers of treatment for musculoskeletal disorders in people with diabetes. In individuals with type 2 diabetes performing moderate exercise, blood glucose levels tend to decline. In individuals with impaired fasting glucose, resistance exercises has shown to lower fasting blood glucose levels 24 hours after exercise. Combined aerobic and resistance training may be more effective for blood glucose management than either type of exercise alone [14]. There is hardly any evidence to suggest the combined effect of physiotherapist-designed supervised exercise protocol of aerobic, resistance & flexibility training on muscle strength and autonomic parameters. The present study aimed to evaluate the combined effect of physiotherapist designed supervised exercise protocol of aerobic, resistance & flexibility training for a period of two weeks on muscle strength, and autonomic parameters in subjects with type 2 diabetes mellitus and compare their values at baseline, 7th day and 14th day respectively.

**METHODOLOGY**

**Participants:** Both males and female subjects willing to participate in the study with age group of 18-65 years, diagnosed with type II diabetes mellitus for more than three years and referred to physiotherapy department were recruited during the study period extending from February 2012 to January 2013.Subjects were excluded if they suffered from illnesses and conditions that were contraindicated for exercise training as per American College of Sports Medicine guidelines [15]. Subjects were excluded if they suffered from chronic renal failure, movement disorders, sensory loss/diabetic neuropathy, any mental illness and /or on renal dialysis. Ethical approval for the study was granted by the Institutional Ethical Committee and the procedures were conducted according to the declaration of Helsinki.

**Study design:** The study was a pre post experimental design with a non-probability sample design, using a convenient sampling
method with $\alpha$ error of 80 and level of significance of $p<0.05$ and assuming a fall out rate of 15% of the subjects recruited in the study.

**Procedure:** After obtaining a written consent from each subject, was screened based on the inclusion and exclusion criteria. The demographic data and the baseline parameters for strength of large muscle groups, and autonomic parameters were taken.

Fig. 1: Physiotherapist designed exercise protocol.

**Physiotherapist Designed Supervised Exercise Protocol:**

**Flexibility training:** 10 minutes of warm up exercises included active stretching of the major muscle groups of the upper and lower body including Deltoid / Posterior Shoulder Stretch, Pectoralis Major / Anterior Capsule Stretch Standing Sleeper Stretch, Rhomboid / Posterior Shoulder Stretch, Supraspinatus / Superior Capsule Stretch, Triceps / Inferior Capsule Stretch Seated calf stretch Kneeling Tibialis anterior stretching Seated Straddle with Side Reaches were given. Two sets with 10 seconds hold in each position was performed for each of the nine stretching exercises. A rest period of 10 seconds was followed after 2 sets. The total stretch protocol lasted for 10 minutes, 6 minutes of which was active stretching. Subjects were instructed to increase the stretch to a point of discomfort, but not pain, and hold for the full 10-second duration [16].

**Aerobics training:** The aerobic training component of the exercise program included level walking on a treadmill at a speed that was correlated to a rating of perceived exertion (RPE) of 12-15 (“somewhat hard”) using the Borg RPE Scale for 10 minutes on the same days as resistance training prescribed. The speed was progressively increased to each patient tolerance during each subsequent training day but did not exceed an RPE of 15.

**Progressive Resistance training (1-RM - Repetition Maximum):** The 1-RM for each exercise was defined as the maximum amount of weight that was performed for one repetition. For 1-RM testing, each subject initially performed one repetition of each exercise with a weight perceived by the participant as “somewhat easy.” Next, each subject rested for 1 to 3 minutes. The physical therapist then increased the weight for each exercise by 1 - 2 kgs. Each subject then attempted to perform another repetition of each exercise. The 1-RM testing procedures for each exercise were continued until each participant either failed to perform one repetition or voluntarily stopped the 1-RM testing procedures. For each subject, muscular strength was expressed as 1-RM (in kilograms) for each exercise. For all subjects, muscular strength testing was conducted at...
baseline, 7th day and 14th day respectively. Resisted training components of the exercise program was consisted of 3 sets of 10 repetitions for all upper-body exercises and for all lower body exercise using (30-80%) of the repetition maximum (1-RM) which was less than 1 minute. The progressive resistance training exercises consisted of six exercises that included arm curls [17], triceps curls [23], chest press [17] (performed on multigym exerciser), knee extensions and knee flexion [17] (knee exercises were performed using quadriceps table), and back extension [17].

Cool down exercises: 5 minutes of cool down exercises was given all in the form of stretching exercises as in warm up exercises with low intensity and 2 repetitions each.

Main outcome measures:
1.RM (Repetition Maximum): 1-RM of the subject was calculated at baseline. Progressive resistance training was given to the subject and again 1-RM was recorded at 7th and 14th day respectively.

2.Autonomic parameters: Autonomic parameters like systolic blood pressure (SBP), diastolic blood pressure (DBP), pulse pressure (SBP-DBP), mean arterial pressure (DBP + 1/3 pulse pressure), pulse rate (beats/minute), respiratory rate (breath cycles/minute) and Rate Pressure Product (RPP= heart rate × SBP × 10−2) was recorded at baseline, 7th day and 14th day respectively.

Statistical analysis: The data of this study were analyzed for muscle strength in terms 1-Repetition Maximum (1-RM), and autonomic parameters in terms of systolic blood pressure, diastolic blood pressure, Pulse pressure, mean arterial pressure, respiratory rate, pulse rate, rate pressure product. Differences in all outcome measures pre exercise and post exercise at baseline, 7th day, 14th day, were compared so as to evaluate the effectiveness of exercise training protocol. Statistical analysis of the data was done using “SPSS” windows version 16.0. Student paired ‘t’ test was used to compare the results at baseline, 7th and 14th day respectively. Student unpaired ‘t’ test was used to compare the results of pre and post exercise and right side and left side joint range of motion. Wilcoxon signed rank test was used depending on the nature of the data. Nominal data comprising subject’s demographic data were analyzed using percentage values. Probability value (p) less than or equal to 0.05 were considered statistically significant.

Table 1: Demographic data of the subjects in the study.
### Table 2: Comparison of mean differences of 1-Repetition maximum in (kgs) at Baseline, 7th day, 14th day in all subjects.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean and SD</th>
<th>Mean and SD Difference</th>
<th>Paired t and p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BL</td>
<td>7th day</td>
<td>14th day</td>
</tr>
<tr>
<td>Arm curls</td>
<td>6.17 ± 1.48</td>
<td>6.73 ± 1.49</td>
<td>7.57 ± 1.56</td>
</tr>
<tr>
<td>Triceps curls</td>
<td>5.42 ± 1.44</td>
<td>5.95 ± 1.43</td>
<td>6.77 ± 1.43</td>
</tr>
<tr>
<td>Chest press</td>
<td>14.42 ± 4.82</td>
<td>15.1 ± 4.82</td>
<td>16.1 ± 4.91</td>
</tr>
<tr>
<td>Knee flexion</td>
<td>8.48 ± 3.1</td>
<td>9.42 ± 2.98</td>
<td>10.25 ± 2.9</td>
</tr>
<tr>
<td>Knee Extension</td>
<td>7.32 ± 2.14</td>
<td>7.93 ± 2.2</td>
<td>8.75 ± 2.19</td>
</tr>
<tr>
<td>Back extension</td>
<td>3.03 ± 0.49</td>
<td>3.47 ± 0.63</td>
<td>3.63 ± 0.49</td>
</tr>
</tbody>
</table>

*Level of significance p < 0.05

### Table 3: Comparison of mean differences between pre and post exercise of Baseline 7th day, 14th day of Autonomic parameters in all subjects.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean and SD</th>
<th>Paired t &amp; p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPP</td>
<td>135.07 ± 5.14</td>
<td>144.33 ± 4.33</td>
</tr>
<tr>
<td>DBP</td>
<td>80.53 ± 3.55</td>
<td>89.07 ± 4.22</td>
</tr>
<tr>
<td>PP</td>
<td>49.73 ± 5.06</td>
<td>53.97 ± 4.87</td>
</tr>
<tr>
<td>MAP</td>
<td>101.96 ± 3.28</td>
<td>107.84 ± 3.84</td>
</tr>
<tr>
<td>SBP</td>
<td>87.83 ± 6.08</td>
<td>99.47 ± 6.24</td>
</tr>
<tr>
<td>RR</td>
<td>16.3 ± 1.37</td>
<td>20.23 ± 2.51</td>
</tr>
<tr>
<td>RPP</td>
<td>118.98 ± 11.49</td>
<td>143.33 ± 10.66</td>
</tr>
</tbody>
</table>

*Level of significance < 0.05

### Results

A total of 65 subjects with type 2 diabetes mellitus referred to the physiotherapy OPD during the study recruitment period were screened, out of which 40 were enrolled into the study based on the eligibility criteria. Thirty (30) subjects completed the follow up. The results of the study were based on the data analyzed for 30 type 2 diabetes mellitus subjects who completed exercise training protocol lasting for two weeks. A total of 28 males (93.33%) and 2 females (6.66%) participated in the present study showing a heterogeneous distribution. The average age of all the subjects was 51.8±8.00 years, with majority of subjects in the age range of 51 - 60 years followed by 41 to 50 years and 61 to 65 years. 28 (93.33%) subjects were males.
and 2 (6.66%) were females in the study. Mean body mass index of all the subjects was 25.59 ± 2.92 kg/m² & found to be overweight criteria as per WHO classification of overweight and obesity. Difference in 1 Repetition Maximum (in kgs) between the baseline & 7th day, BL & 14th day and 7th and 14th day showed statistical significant improvement from baseline to the 7th day in all 1 RM variables i.e arm curls, triceps curls, chest press, knee flexion (Hamstrings) & knee extension (Quadriceps) & back extension respectively. All autonomic parameters demonstrated significant differences pre and post exercises at baseline, 7th day and 14th day respectively.

DISCUSSION

The present study was conducted to study the impact of physiotherapist designed supervised exercise training protocol on muscle strength, and autonomic parameters in patients with type 2 diabetes. Thirty subjects completed the training protocol. The subjects recruited in the study were in age range from 31 - 65 years (56.6%) and maximum number of subjects recorded was 51- 60 years (56 %). The prevalence of type 2 diabetes mellitus is well documented in this age group. However, the group of 40-59 years currently has the greatest number of persons with type 2 diabetes mellitus. The estimates for 2003 and 2025 have shown a female predominance in the number of persons with diabetes. Majority of the population based multicentric studies reported similar prevalence of diabetes in males and females [18]. However, in the present study the percentage of males was more than females showing a heterogeneous distribution.

Mean BMI of all the subjects were in the category of overweight which may be correlated with a study carried out by Ramachandran A et al which reported that diabetes occurred at lower BMI levels in Asians than in western populations [19]. And small increments in weight triggers glucose intolerance in susceptible subjects. Asian Indians have high glucose intolerance which account for the high prevalence of insulin resistance diabetes at low levels of BMI. Risk of diabetes has shown to increase progressively from a BMI of ≥ 23 kg/m² among Indians. 33 BMI of ≥ of 23 kg/m² is also considered overweight for most Asian populations [20,21].

Hypertension is a risk factor for the development of type 2 diabetes mellitus. Patients with hypertension are at a 2–3 times higher risk of developing diabetes than patients with normal blood pressure [22]. A survey by Bays H. E. et al reflect and support the common clinical observation that patients with higher BMI are at higher risk for having diabetes mellitus, hypertension and dyslipidaemia [23]. History of smoking of the subjects in the present study may be correlated by findings of a study conducted by Willi et al suggesting that the risk of diabetes was higher among smokers than non-smokers [24]. Smoking has also shown to increase the risk of central obesity and insulin resistance with several other deleterious effects of nicotine exposure [25]. People with non-vegetarian diet (or mixed diet) are at risk for the development of obesity which is one of the risk factors for development of diabetes. Vegetarian diets may play a beneficial role in promoting health and preventing obesity [26].

RPE (rating of perceived exertion scale) is a method for prescribing exercise intensity in a diabetic population. It is a subjective tool that may be used in place of heart rate, and its use has been the recommended for patients with diabetic autonomic neuropathy. In normal populations, use of the RPE scale has been validated for level treadmill running. RPE has shown to be useful in clinical settings where maximal or peak heart rate cannot be easily measured and where heart rate reserve (HRR) is not routinely used. In the present study exercise intensity was monitored using RPE with intensity of 12-15. It is recommended that those with type 2 diabetes engage in physical activity at a comfortable level (RPE 10–12) [27].

With respect to muscle tissues, diabetes affects primarily cardiac cells which can trigger several adaptive and maladaptive responses that are evident in diabetic cardiomyopathy [28]. Hyperglycemia also can lead to an enhanced synthesis of vasoconstrictor prostanoids by the endothelium and activation of protein kinase C. This can promote abnormal capillary permeability, microaneurysm formation, subendothelial...
matrix deposition, and fibrosis surrounding arterioles leading to myocardial hypertrophy, endothelial dysfunction, and ventricular hypertrophy. The skeletal musculature is also significantly affected in diabetic complications like contractile weakness, fiber-type changes, decreased oxidative activity and peripheral insulin resistance [29]. Muscle is the most important insulin-dependent glucose link in the body hence, impairing hormonal signaling and having deleterious effect on glucose uptake [30]. There is a linear relationship of longer duration of diabetes and poor glycemic control which are associated with much poorer muscle quality and neuropathic processes involving motor neurons that might be a possible underlying mechanism for the poor muscle function in diabetes [31]. It has been reported that older women with type 2 diabetes are at high risk for loss of skeletal muscle mass compared to men [32]. Skeletal muscle strength especially in the lower extremity, is generally lower in adults with diabetes than in non-diabetic subjects. In the present study muscular strength was assessed by 1-repetition maximum. Though actual 1-RM testing is the most reliable test for evaluating the maximal dynamic strength of a muscle or group of muscles untrained subjects may not always be able to reach their 1-RM [33]. Leuser DA et al suggested that actual 1-RM muscle strength testing may be contraindicated in individuals who have no previous lifting experience. However, Altman B has suggested that 1-RM method can be used in assessing muscular strength in subjects with type II diabetes mellitus. Validity of this method has been established in measuring muscle strength in exercises such as the bench press, squat, dead lift, triceps press, bicep curl, leg press, hip flexion, hip extension, hip abduction, hip adduction, planter flexion, and dorsiflexion [35].

The present study demonstrated an increase in muscular strength of biceps, triceps, and knee flexor and extensor and back extenders using the same method. Two sessions per week of progressive resistance training (PRT) has demonstrated significant improvement in insulin sensitivity and fasting glycemia and decreasing abdominal fat in older men with type 2 diabetes and other CVD risk factors [36]. Supervised resistance training has shown to improve glycemic control and insulin sensitivity however, when supervision was removed compliance and glycemic control decreased [37].

Flexibility exercises should be incorporated into the overall fitness program sufficient to develop and maintain range of motion (ROM). These exercises should be performed to the major muscle groups for a minimum of 2–3 d.wk⁻¹. Present study included the static active stretching exercises for both upper and lower body. Combined aerobic and resistance training has shown to improve maximal and sub-maximal exercise capacity, body composition, muscular strength and glycemic control in type 2 diabetic subjects, peak while sub-maximal RPP and HR decreased following training. Combined method of this type of training suggested increase in cardiovascular fitness and skeletal muscle capillary density and reduction in body fat and resistance exercise has shown to improve muscle mass and strength [37].

Elevated blood pressure is 1.5-2 times more prevalent in people with diabetes than it is in the general population and most elderly people with Type 2 diabetes require blood pressure lowering therapy. Elevated blood pressure in people with Type 2 diabetes may indicate evolving diabetic nephropathy or part of the metabolic syndrome. In elderly subjects, elevated blood pressure is often confined to an isolated elevation of systolic blood pressure. If not associated with diabetic nephropathy, an elevated blood pressure may precede the development of Type 2 diabetes [38]. In young people, a rise in blood pressure affects systolic and diastolic blood pressure in parallel. By contrast, in older people the most common pattern is a rise in systolic and a fall in diastolic blood pressure leading to a rise in pulse pressure which may itself be involved in the pathogenesis of vascular events [39]. Seamus P. et al suggested aerobic activity lasting for at least 2 weeks reportedly changed both systolic and diastolic blood pressures suggesting that an increase in physical activity should be an important component of lifestyle modification for prevention and treatment of high blood pressure [40]. Reduction in systolic blood pressure and diastolic blood pressure in the
The present study is consistent with the findings of the previous study conducted by McCartney N suggesting resistance training decreases acute systolic blood pressure, diastolic blood pressure and rate pressure product in response to weight lifting by 17-27% [41]. Heart rate is primarily mediated by the direct activity of the autonomic nervous system with predominance of vagal activity (parasympathetic) at rest that is progressively inhibited from the onset of exercise. Studies suggest that aerobic training causes a lower resting heart rate due to higher parasympathetic activity. Regular supervised exercise has shown to significantly improve heart rate variability in patients with type 2 DM which may favorably influence their long-term prognosis suggesting that vagal tone increases after training [42]. This may be the reason for significant decrease in heart rate in subjects with type 2 diabetes mellitus following exercise protocol in the present study.

Rate pressure product (RPP) is an easily measurable index which correlates well with myocardial oxygen demand and defines the response of coronary circulation to myocardial metabolic demands [43]. Heart rate and pulse pressure have been used to predict cardiovascular risk. Heightened resting RPP and failure of RPP increment during cardiac sympathetic stimulation has shown to promote aggravated ischemic episodes rendering autonomic neuropathy diabetics vulnerable to adverse cardiovascular events leading to increased morbidity and mortality [44].

Present study demonstrated reduction in RPP and heart rate which is consistent with the findings of a study by Maiorana A et al suggesting submaximal RPP and HR decreased following training indicating that subjects could exercise at higher submaximal exercise intensities prior to the onset of blood lactic acid accumulation [37].

To conclude, the present study demonstrated that physiotherapist designed supervised exercise training protocol in the form of aerobic resistance and flexibility training was effective in increasing muscle strength in terms of 1 RM and improving autonomic parameters. Though the study had a small sample size and a short follow up period of two weeks, clinical trials with larger sample size with homogenous population and longer follow-up period to assess long term benefits and determining the effect on glycolated hemoglobin may be further suggestions as future scope of research.

Note: This study is a part of a post graduate dissertation project with Clinical trial registry in India (CTRI) number: CTRI/2013/06/003731

Conflicts of interest: None

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