Content available at: iponlinejournal.com

Indian Journal of Clinical Anatomy and Physiology

Journal homepage: www.innovativepublication.com

Original Research Article

Impact of lifestyle modifications on obesity and biochemical parameters at different time intervals in newly diagnosed patients with type 2 diabetes mellitus – A randomized controlled trial

Harpreet Kour[1],*, Shivaprasad Goudar[1], V A Kothiwale[1]

[1] *Dept. of Physiology, J N Medical College, Belagavi, Karnataka, India*

ARTICLE INFO

Article history:
Received 12-06-2019
Accepted 24-09-2019
Available online 12-10-2019

Keywords:
Type 2 Diabetes Mellitus
Structured Exercise Therapy
Lifestyle modification

ABSTRACT

Introduction and Objectives: Diabetes Mellitus is complex metabolic disorder and have appeared as gigantic public health problem worldwide. The prevalence of specifically type 2 diabetes mellitus is increasing in adult population due to sedentary lifestyle and more junk food consumption leading to obesity. This further is linked with decreased insulin sensitivity of the tissues and insulin resistance which is major indicator of type 2 diabetes mellitus. Lifestyle modifications are considered as one of the important cornerstone in management of diabetes mellitus. Therefore present study has been undertaken to assess, in a randomized manner, the impact of life style modification in form of structured exercise therapy on anthropometric and biochemical parameters in young adults newly diagnosed with type 2 diabetes mellitus.
Materials and Methods: Total of 148 patients of age group 20-45 years with newly diagnosed T2DM were enrolled in the study as per eligibility criteria. The patients were divided randomly into two groups as Diabetic controls and interventional group. Socio-demographic, Anthropometric and Biochemical parameters were evaluated at baseline and at the end of six months for the study groups. Whereas the impact of lifestyle modification is studied at different time intervals, .i.e at baseline and at the end of 2nd, 4th and 6th months were studied. P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.
Results: There was significant improvement found in majority of anthropometric and biochemical parameters in intervention group at the end of six months of structured exercise therapy.

© 2019 Published by Innovative Publication.

1. Introduction

The prevalence of type 2 diabetes mellitus is in rise among adult population. There is a paradigm shift as type 2 diabetes mellitus was called as disease of elderly and currently include huge amount of adult population also. The pathophysiology of type 2 diabetes mellitus is multifactorial but insulin resistance remains the predominant characteristic. India had almost 31.7 million population diagnosed with type 2 diabetes mellitus in the year 2000 and it is estimated to be more than doubled viz; around 79.4 million in year 2030. Now India is known as Capital of Diabetes. This actually is an alarming scenario for Indian health care system to be more vigilant for adequate management of type 2 diabetes mellitus.[1,2]

The main cause of increasing prevalence of type 2 diabetes mellitus includes overweight and obesity among adult population due to westernization, consumption of more junk food, sedentary lifestyles, high calories intake etc. Recently a new term has been coined as "diabesity" emphasizing the strong link between diabetes and obesity.[3,4] High body mass index (BMI), waist circumference (WC), waist-hip ratio (WHR), Hyperglycemia and lipid profile derangements are reported in diabetic population.[5–7]

The lifestyle modification along with dietary therapy and medications are important part of management of cases with type 2 diabetes mellitus. There is growing body of evidence suggesting benefits of various forms of exercises for good blood glucose control and overall management of diabetes mellitus. Targeting young type 2 diabetic patients may

* *Corresponding author.*
E-mail address: harpreetkour.kour@gmail.com (H. Kour).

https://doi.org/10.18231/j.ijcap.2019.062
2394-2118/© 2019 Published by Innovative Publication.

delay the onset and complications of diabetes and provide them with better quality of life.[8–12] Therefore, present study has assessed, in a randomized manner, the impact of life style modification in form of structured exercise therapy on anthropometric and biochemical parameters in young adults newly diagnosed with type 2 diabetes mellitus.

We hypothesized that six months of structured exercise therapy with diet control and anti-diabetic drugs have better improvement among various study parameters. The lesser amount of cost, non pharmalogical characteristics will further enhance its therapeutic utility.

2. Objectives of the study

1. To study the effect of six months of structured exercise therapy on anthropometric and biochemical profile in young adults with newly diagnosed T2DM.
2. To study the effect of structured exercise therapy on study variables at different time intervals among young diabetic patients enrolled in the interventional group.

3. Materials and Methods

The present randomized controlled study was conducted in the Department of Physiology, Jawaharlal Nehru Medical College attached to KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi. All patients diagnosed newly with T2DM from April 2017 to October 2018, from Medicine OPD of Dr. Prabhakar Kore Hospital and Research Centre formed the study material. The study was approved by the Institutional Ethical Committe, and all participants gave informed consent.

3.1. Inclusion criteria

All the patients diagnosed newly with type 2 diabetes mellitus (April 2017 – October 2018) of age group 20-45 years were enrolled. The patients who were treated with only diet and oral anti-diabetics were enrolled.

3.2. Exclusion criteria

Subject with history of Diabetes more than a year or with known chronic diseases restricting physical activity, subjects with prior regimen of physical exercise and also patients who were on any other medication (e.g. antihypertensive, systemic steroid medication etc).

3.3. Sample Size

Was calculated by using the below mentioned formula,

$$\frac{(Z_{1-\beta}+Z_{1-\alpha})^2(SD_1^2+SD_2^2)}{(\bar{x}_1-\bar{x}_2)^2}$$

Where, Z = Standard for test = X-$\overline{X}$/SD, Z_1 -α = at 95%, Confidence Interval = 1.96, Z_{1-}b = at 80%, Power of the test = 1.64, Mean and SD is taken from by review of literature for study and control were taken as 29.3 + 0.84 and 28.7 + 1.69. X1-X2 = Expected impact size. Calculations: n = $(1.64 + 1.96)^2$ $(0.842615^2 + 1.697056^2)$ / $(29.3 + 28.7)^2$ = 130 Accounting drop out cases as 10%, then the calculated sample size was = 132/ 0.9 = 144.4 - rounded to 146. So total of 146 diabetic patients were enrolled.

Randomization: The patients were then randomly divided into Diabetic group and Interventional Group by computer generated, randomized number sequence. This randomization allocation was placed in Opaque Sealed Envelopes.

Groups: Two groups were made. First one was Diabetic controls which included patients with dietary control and anti- diabetic drugs. Second group was Interventional Group which included patients with dietary control, anti-diabetic drug and structured exercise therapy. Figure 1

Lifestyle Modification Programme included six months of individually designed structured exercise therapy including aerobic and resistance exercises. The aerobic exercises included 30 minutes of activity, five days per week. Resistance exercise included nine sets viz: seated single leg extension, dumbbell flies, dumbbell bent over row, dumbbell shoulder press, dumbbell upright row, standing leg curls, dumbbell biceps curls, abdominal curls and dumbbells triceps kick bags. All the patients enrolled in interventional group were given printed individualized instructions and dumbbells of 2kgs weight. The patients were also taught stretching exercise and were instructed to perform the same after very session.[13,14]

3.4. Study variable

3.4.1. Socio-demographic

Age in years was noted to the nearest completed year as determined from their Ration card/ Driving License/Adhar Card.

3.4.2. Socio economic status

Was evaluated by taking education, occupation and family income into account and scoring them as per Kuppuswamy's score card.

3.4.3. Anthropometric measurements

Height in cms, weight in kgs Body Mass Index in kg/m^2(BMI), Body Fat %, Skin fold thickness in mm (SFT), Waist Circumference in cms (WC), Hip circumference in cms (HC) and Waist Hip ratio (WHR) were measured as per standard protocols. The categorization of the BMI was done according to the BMI criteria for the Indian population and was calculated by quelets Index. Body Fat was calculated using Siri's Equation. Skin Fold Thickness from seven sites was measured by Herpenden skin fold calipers (Anand agencies, Pune). Waist-Hip Ratio (WHR) was calculated with the corresponding values of waist circumference divided by the hip circumference. Waist-Hip ratio of $\geq$ 1.0 for males and $\geq$ 0.85 for females was considered as truncal obesity. Waist circumference $\geq$ 90 cm in males and $\geq$ 80 cm in females was considered as central Obesity/ abdominal obesity.

3.4.4. Biochemical parameters

Venous blood was drawn for Glucose Profile included Fasting Blood Glucose mg/dl (FBG), Post Prandial Blood Glucose mg/dl (PPBG) and Glycated Hemoglobion% (HbA1c). Lipid Profile included Total Cholesterol mg/dl (TC), Low Density Lipoprotein mg/dl (LDL), High Density Lipoprotein mg/dl (HDL), Total Triglycerides mg/dl (TG) and Very low Density Lipoproteins mg/dl (VLDL). All the parameters were determined in the serum of the subjects by using commercially available reagent kits. The lipid profile of the subjects was classified, based on the Adult Treatment Panel III model of National Cholesterol Educational Program and glycemic control as per criteria laid by American Diabetes Association 2018. The American Diabetes Association (ADA) proposed HbA_1 C $\geq$6.5% for the diagnosis of diabetes and 5.7-6.4% for the highest risk to progress to diabetes. [15,16]

3.5. Statistical methods

Descriptive analysis was carried out by mean and standard deviation.. For normally distributed Quantitative parameters the mean values were compared between study groups using Independent sample t-test. The change in the quantitative parameters, before and after the intervention was assessed by paired t-test (In case of two time periods) or one-way repeated measures ANOVA (In case of comparison across more than 2 time periods). One-way repeated measures ANOVA was used to assess the statistical significance of differences in the normally distributed quantitative variables, measured within intervention group, at different time periods. P value $<$ 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

4. Results

Out of the secondary outcome variables height, Body density, Body fat (%), Waist circumferences, Hip circumferences, waits hip ratio, Physical Fitness Index, VO2 Max, Basel heart rate, Max. HR beats/min, SBP, DBP and biochemical parameter (Hb (%), FBS (mg/dl), PPBS, HbA1c(mg/dl), Triglycerides (mg/dl), Total Cholesterol (Mg/Dl), HDL (Mg/Dl), LDL (Mg/Dl) and VLDL (Mg/Dl)) were comparable between intervention group and diabetic control group at baseline (P value >0.005). (Table 2)

The mean weight, BMI, skin fold thickness, waist circumference, hip circumference and waist hip ration were significantly improved in the intervention group at the end of six months of exercise therapy. Body fat % did not show any statistically significant difference between diabetic controls and intervention groups. (Table 3)

Out of the laboratory parameters, total Cholesterol and LDL were comparable between the diabetic control at end of 6^{th} month and intervention at end of 6^{th} month which have shown no statistically significant (P value >0.05). Out of the biochemical parameters, Hb%, total Cholesterol and LDL were comparable between the diabetic control at end of 6^{th} month and intervention at end of 6^{th} month which have shown no statistically significant (P value >0.05). The mean FBS (104.74 $\pm$ 11.44 Vs 89.88 $\pm$ 5.69, P value <0.001), the median PPBS (140 Vs 132, P value <0.001) and the mean HbA1c (5.86 $\pm$ 0.37 Vs 5.14 $\pm$ 0.36. P value <0.001) were significantly lower in the intervention group, as compared to control group, at the end of 6 months follow up period. The mean Triglycerides (151.36 $\pm$ 12.6 Vs 158.18 $\pm$ 14.66, P value =0.001) and VLDL (30.27 $\pm$ 2.52 Vs 30.27 $\pm$ 2.52, P value= 0.003) were lower and the mean HDL was higher (45.39 $\pm$ 7.24 Vs 31.64 $\pm$ 2.93, P value 0.049) among the intervention group, at the end of 6^{th} month follow up period. (Table 4)

Among the anthropometric parameters and laboratory parameters, which have shown statistically significant improvement, all the components, except waist circumference and waist hip ratio had shown statistically significant improvement in the first 2 months following the intervention. No statistically significant decline/change was observed in BMI, HbA1c, waist circumference, triglycerides, VLDL and HDL levels between 2^{nd} to 4^{th} month and 4^{th} to 6^{th} month post intervention period. But Skinfold thickness had shown a statistically significant decline between 2^{nd} to 4^{th} month and 4^{th} to 6^{th} month post intervention period. Few parameters like waist hip ratio, basal heart rate and PPBS have shown statistically significant improvement between 2^{nd} to 4^{th} month, and not much significant change after 4^{th} month. (Tables 5 and 6)

5. Discussion

The study population consisted of adult subjects aged 20-45 years newly diagnosed with type 2 diabetes mellitus. Diabetes mellitus, more simply called diabetes, is a "chronic condition that occurs when there are raised levels of glucose in the blood because the body cannot produce any or enough of the hormone insulin or use insulin effectively.[17] Diabetes has emerged as a major global public health problem and is a major contributor for global mortality. Along with other three major noncommunicable diseases (NCDs) (cardiovascular disease, cancer and respiratory disease) it contributes to more than 80% premature NCD related mortality.[18] As per the estimates, there are 451 million (age 18-99 years) people with diabetes globally in the year 2017, which is expected to raise to 693 million by 2045. This is in addition to approximately 374 million people with impaired glucose tolerance (IGT). In 2017, close 5 million deaths globally were attributed to diabetes among people

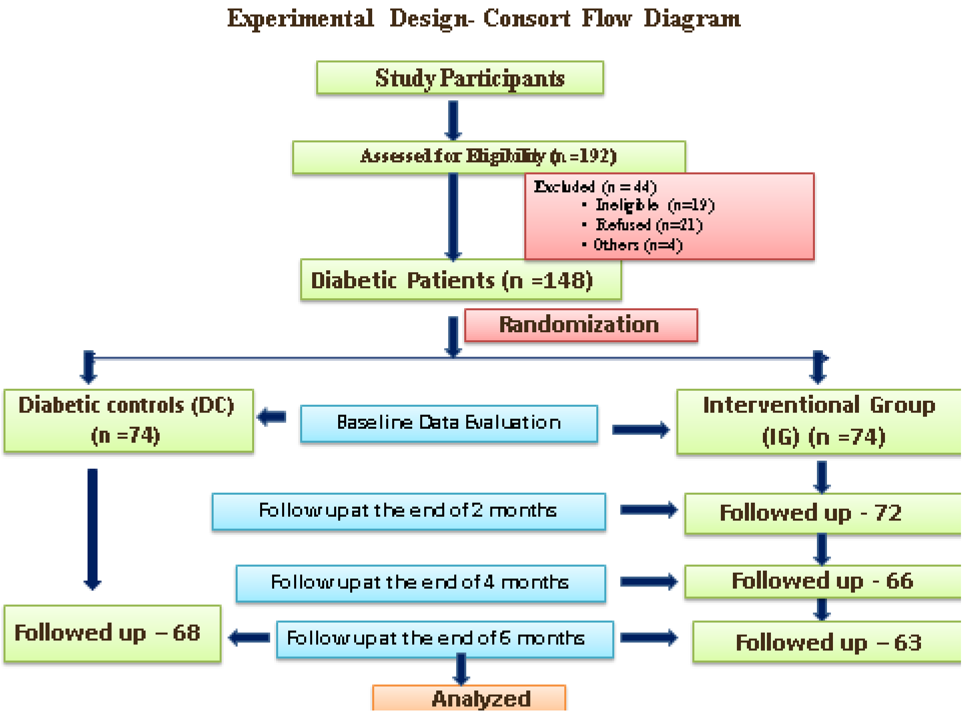

Fig. 1:

Table 1: Socio-demographic parameters between Diabetic control and intervention groups

Parameter	Diabetic control at baseline (N=74)	Intervention group at baseline (N=74)	P Value
Age (mean ± SD)	37.46 ± 4.06	36.95 ± 4.13	**0.447**
Gender			
Male	40 (54.05%)	42 (56.75%)	**0.741**
Female	34 (45.94%)	32 (43.24%)	
Socio economic status			
Upper Middle	28 (37.83%)	25 (33.78%)	
Lowe Middle	30 (40.54%)	35 (47.29%)	**0.865**
Upper Lower	12 (16.21%)	10 (13.51%)	
Lower	4 (5.405%)	4 (5.405%)	
Religion			
Hindu	37 (50%)	41 (55.40%)	
Muslim	33 (44.59%)	32 (43.24%)	**0.364**
Christian	4 (5.405%)	1 (1.351%)	

All the demographic variables including age, gender, socio economic status and religion were comparable between intervention group and diabetic controls group at baseline (P value >0.005). (Table 1)

aged between, 20-99 years. The global economic burden was estimated to be USD 850 billion in 2017.[19]

5.1. *Anthropometric parameters*

In the current study, the mean weight and BMI were significantly lesser in the intervention group at 6-month period following the intervention. The mean weight in control group was at end of 6th month was 80.7 ± 6.57, and in intervention group it was 72.32 ± 8.35(P value <0.001). The mean BMI of subjects in control group was 31.04 ± 3.39, and in intervention group it was 27.45 ± 3.29. (P value <0.001). The other parameters, which have shown statistically significant difference between the intervention and control groups were median skin fold thickness (241 (IQR 236 to 248.25 Vs 235 (IQR 230 to 242), P value < 0.001), Waist circumference (91.17 ± 5.89 Vs 88.65 ± 6.26, P value 0.013) and waits hip ratio (1.01 ± 0.07 Vs 0.98 ± 0.045 P value 0.003). Body density and body fat % did not show any statistically significant difference between

Table 2: Anthropometryand Biochemical parameters between diabetic controlgroup and intervention group at baseline after randomization

Parameters	**Diabetic Control baseline (DC) (N=74)**	**Intervention group at baseline (N=74)**	**P Value**
Height (cms) (mean ± SD)	161.85 ± 6.25	162.49 ± 6.39	*0.542*
Weight (Kgs) (mean ± SD)	83.62 ± 6.51	80.32 ± 8.15	*0.007*
BMI (kg/m^2)(mean ± SD)	32.03 ± 3.22	30.5 ± 3.33	*0.005*
Skin Fold Thickness (mm) (median)	241.5 (236.75, 248.25)	246 (239, 253)	0.034
Body fat (%) (Median IQR)	32.85(31.55, 39.19)	33.01 (31.68, 39.35)	0.565
Waist circumferences (cms)	92.45 ± 6.28	93.22 ± 5.89	*0.443*
Hip circumferences (cms)	92.12 ± 8.3	91.98 ± 8.21	*0.917*
Waist hip ratio	1.01 ± 0.07	1.02 ± 0.06	*0.368*
Biochemical			
Hb (%)	13.49 ± 1.37	13.58 ± 1.29	*0.662*
FBG (mg/dl)	104.8 ± 11.96	106.09 ± 10.49	*0.484*
PPBG (mg/dl) (Median)	138.5 (130, 146)	140 (138, 146.5)	0.118
HbA1c (%)	5.97 ± 0.48	5.93 ± 0.46	*0.542*
Triglycerides (mg/dl	156.92 ± 14.53	156.64 ± 15.14	*0.908*
Total Cholesterol (mg/dl)	220.61 ± 25.88	218.54 ± 27.32	*0.637*
HDL (mg/dl)	43.34 ± 7.53	41.12 ± 6.91	*0.064*
LDL (mg/dl)	145.89 ± 27.92	146.09 ± 29.87	*0.966*
VLDL (mg/dl)	31.38 ± 2.91	31.33 ± 3.03	*0.908*

Among the anthropometric parameters, BMI and Skin Fold Thickness (cms) were significantly higher among the control group, as compared to intervention group. (Table 2)

Table 3: Comparison of anthropometry parameters between diabetes control group and intervention group at end of 6th months

Parameter	**Diabetic Control at the end of 6th month (NC) (N=68)**	**Intervention group at end of 6th month (N=63)**	**P Value**	**Parameter**
Anthropometry				
Height (cms) (mean ± SD)	161.62 ± 6.44	162.49 ± 6.39	0.414	
Weight (Kgs) (mean ± SD)	80.76 ± 6.57	72.32 ± 8.31	0.001	
BMI (kg/m^2) (mean ± SD)	31.04 ± 3.39	27.45 ± 3.29	0.001	
Skin Fold Thickness (mm) (median)	241 (236, 248.25)	235 (230, 242)	0.001	
Body fat (%) (Median IQR)	32.81 (31.53, 39.24)	32.5 (30.81, 39.01)	0.169	
Waist circumferences (cms)	91.17 ± 5.89	88.65 ± 6.26	*0.013*	
Hip circumferences (cms)	91.01 ± 8.19	91.14 ± 7.87	*0.919*	
Waist hip ratio	1.01 ± 0.07	0.98 ± 0.05	*0.003*	

Table 4: Comparisonof Biochemical parameters between diabetes control group and intervention group at end of 6thmonths

Parameter	**Diabetic Control at the end of 6th month (NC) (N=68**	**Intervention group at end of 6th month (N=63)**	**P Value**
Biochemical parameters			
Hb (%)	13.3 ± 1.3	13.5 ± 1.35	*0.372*
FBG (mg/dl)	104.74 ± 11.44	89.88 ± 5.69	<0.001
PPBG (mg/dl) (Median)	140 (131.5, 144.5)	132 (127, 137)	<0.001
HbA1c (%)	5.86 ± 0.37	5.14 ± 0.36	<0.001
Triglycerides (mg/dl)	158.18 ± 14.66	151.36 ± 12.6	*0.003*
Total Cholesterol (mg/dl)	218.73 ± 26.95	215.61 ± 20.54	*0.429*
HDL (mg/dl)	43 ± 7.42	45.39 ± 7.24	*0.049*
LDL (mg/dl)	144.09 ± 28.84	139.94 ± 21.31	*0.321*
VLDL (mg/dl)	31.64 ± 2.93	30.27 ± 2.52	*0.003*

**Mean ± SD of Normally distributed quantitative variables were compared using independent sample t-test, median & Inter quartile rage (IQR) of non-normally distributed quantitative variables were compared using Mann-Whitney U test. Categorical variables were compared using Chi-square test*

Table 5: Comparison of trend of various secondary outcome parameters in the intervention group from baseline to post intervention

Parameter	Interventional Group Baseline (IG) (N=74)	Interventional Group, At the end of 2 months (IG) (N=72)	Interventional Group, At the end of 4 months (IG) (N=66)	Interventional Group, At the end of 6 months (IG) (N=63)	
Anthropometry					
Height (cms) (mean ± SD)	162.49 ± 6.39	162.49 ± 6.39	162.49 ± 6.39	162.49 ± 6.39	1.000
Weight (Kgs) (mean ± SD)	80.32 ± 8.15	76.73 ± 8.12	74.42 ± 8.29	72.32 ± 8.31	<0.001
BMI (kg/m^2) (mean ± SD)	30.5 ± 3.33	29.13 ± 3.25	28.25 ± 3.27	27.45 ± 3.29	<0.001
Skin Fold Thickness (mm) (median)	246.68 ± 11.41	242.69 ± 10.91	239.84 ± 11.1	236.65 ± 11.65	<0.001
Body fat (%)	35.22 ± 4	34.88 ± 3.98	34.71 ± 4.06	34.66 ± 4.35	0.840
Waist circumferences (cms)	93.22 ± 5.89	91.93 ± 6	90.42 ± 5.91	88.65 ± 6.26	<0.001
Hip circumferences (cms)	91.98 ± 8.21	91.94 ± 8.17	91.64 ± 7.98	91.14 ± 7.87	0.916
Waist hip ratio	1.02 ± 0.06	1.02 ± 0.06	1.02 ± 0.06	1.02 ± 0.06	<0.001
Biochemical parameters					
Hb (%)	106.09 ± 10.49	92.31 ± 5.35	89.41 ± 5.47	89.88 ± 5.69	<0.001
FBG (mg/dl)	141.99 ± 9.92	128.84 ± 8.63	133.3 ± 7.72	132.14 ± 7.01	<0.001
PPBG (mg/dl) (Median)	5.93 ± 0.46	5.15 ± 0.38	5.16 ± 0.37	5.14 ± 0.36	<0.001
HbA1c (%)	156.64 ± 15.14	150.07 ± 11.71	154.22 ± 14.69	151.36 ± 12.6	0.017
Triglycerides (mg/dl)	218.54 ± 27.32	215.19 ± 22.92	215.19 ± 22.92	215.61 ± 20.54	0.790
Total Cholesterol (mg/dl)	41.12 ± 6.91	45.5 ± 6.58	46.22 ± 6.65	45.39 ± 7.24	<0.001
HDL (mg/dl)	146.09 ± 29.87	139.68 ± 25.2	138.13 ± 24.75	139.94 ± 21.31	0.240
LDL (mg/dl)	31.33 ± 3.03	30.01 ± 2.34	30.84 ± 2.94	30.27 ± 2.52	0.017

**One-way repeated measures ANOVA was used to compute the statistical significance of differences in normally distributed quantitative variables at different follow up periods*

Table 6: Significance of pairwise differences between at different follow up peiods in secondary outcome variables

Significant variables	Baseline Vs 2 months	Baseline Vs 4 months	Baseline Vs 6 months	2 months Vs 4 months	2 months Vs 6 months	4 months Vs 6months
Weight (kgs)	0.008	<0.001	<0.001	0.088	0.001	0.122
BMI (kg/m^2)	0.012	<0.001	<0.001	0.104	0.002	0.142
Skin Fold Thickness (mm)	0.032	<0.001	<0.001	0.125	0.001	0.086
Waist circumferences (cms)	0.193	0.005	<0.001	0.129	0.001	0.075
Waist Hip Ratio	0.126	0.003	<0.001	0.153	0.003	0.112
FBS (mg/dl)	<0.001	<0.001	<0.001	0.013	0.038	0.685
PPBS (mg/dl) (Median)	<0.001	<0.001	<0.001	0.001	0.017	0.400
HbA1c %	<0.001	<0.001	<0.001	0.983	0.852	0.836
Triglycerides (mg/dl)	0.004	0.281	0.019	0.065	0.562	0.204
HDL (mg/dl)	<0.001	<0.001	<0.001	0.525	0.924	0.465
VLDL (mg/dl)	0.004	0.281	0.019	0.065	0.562	0.204

**Statistical significance of Pairwise differences was computed by paired t-test for normally distributed quantitative variables and Wilcoxon-signed rank test for non-normally distributed quantitative variables.*

control and intervention groups Body density and body fat % did not show any statistically significant difference between control and intervention groups. Among the anthropometric parameters, which have shown statistically significant improvement, all the components, except waist circumference and waist hip ratio had shown statistically significant improvement in the first 2 months following the intervention. No statistically significant decline/change was observed in BMI, waist circumference, between 2^{nd} to 4^{th} month and 4^{th} to 6^{th} month post intervention period. But skinfold thickness had shown a statistically significant decline between 2^{nd} to 4^{th} month and 4^{th} to 6^{th} month post intervention period. Few parameters like waist hip ratio had shown statistically significant improvement between 2^{nd} to 4^{th} month, but not much significant change after 4^{th} month.

Kwon, H. R., et al.,[20] in their study have compared the aerobic and resistance training program on various aspects, among women with Type 2 Diabetes mellitus. Significant reduction in weight was observed with both aerobic (2.8+/-2.5%, P=0.002) and resistance (1.6+/-2.0%, P=0.017) exercises.

A study by Dos Anjos, D., et al.[21] had reported a significant reduction in the anthropometric measures of body mass, BMI and hip circumference, following an aerobic exercise program among diabetic elderly women. A systematic review by Kuhle, C. L., et al.[22] had reported a significant reduction in BMI (-1.01 kg/m(2), 95% CI -2.00 to -0.01) and WC (3.09 cm, 95% CI -4.14 to -2.04) among older adults following with structured exercise programme. Mshunqane, N., et al.[23] have reported significant reduction in weight, BMI, waist circumference following exercise therapy, similar to current study findings. In contrast to the current study findings, Kadoglou, N. P., et al.[24] have reported no significant reduction in any of the anthropometric parameters among diabetic patients following exercise therapy.

Even though there are differences across the studies in the amount of reduction in body weight, BMI and waist circumference, the overall evidence is consistent with respect to impact of exercise on these parameters. These differences again can be partially attributed to variability in terms of nature and intensity of exercise, duration of follow up and the population composition of each study.

5.2. *Biochemical parameters*

In the current study, out of the laboratory parameters, Hb%, total Cholesterol and LDL were comparable between the diabetic control at end of 6^{th} month and intervention at end of 6^{th} month which have shown no statistically significant (P value >0.05). Out of the biochemical parameters, Hb%, total Cholesterol and LDL were comparable between the diabetic control at end of 6^{th} month and intervention at end of 6^{th} month which have shown no statistically significant (P value >0.05). The mean FBS (104.74 ± 11.44 Vs 89.88 ± 5.69, P value <0.001), the median PPBS (140 Vs 132, P value <0.001) and the mean HbA1c (5.86 ± 0.37 Vs 5.14 ± 0.36. P value <0.001) were significantly lower in the intervention group, as compared to control group, at the end of 6 months follow up period. The mean Triglycerides (151.36 ± 12.6 Vs 158.18 ± 14.66, P value =0.001) and VLDL (30.27 ± 2.52 Vs 30.27 ± 2.52, P value= 0.003) were lower and the mean HDL was higher (45.39 ± 7.24 Vs 31.64 ± 2.93, P value 0.049) among the intervention group, at the end of 6^{th} month follow up period. Among the laboratory parameters, which have shown statistically significant improvement, all had shown statistically significant improvement in the first 2 months following the intervention. No statistically significant decline/change was observed in Hba1c, triglycerides, VLDL and HDL levels between 2^{nd} to 4^{th} month and 4^{th} to 6^{th} month post intervention period. PPBS had shown statistically significant improvement between 2^{nd} to 4^{th} month, and not much significant change after 4^{th} month.
Similar to current study findings, a study by Kadoglou, N. P., et al.[24] have reported a significant reduction in HbA(1c) (P<0.05), following an exercise programme. But this study had also reported significant decline in LDL levels, which was in contrast to current study findings. Choi, K. M., et al.[25] also have reported significant reduction in HbA1c level along with LDL levels and various inflammatory markers, as compared to control group following a 60 minute moderate intensity exercise programme, delivered for 5 times a week for 12 weeks. A recent systematic review Byrne, H., et al.[25] had reported quite variable results, with respect to various metabolic outcomes following self-directed exercise therapy among diabetic population. Even though none of the studies have reported worsening of glycemic control as measured by HbA1C, there are few studies which have reported no significant changes in HbA1C values with self-directed exercise therapy. But majority of the studies have reported significant improvement in HbA1c values, following exercise therapy or with control group. Another key finding of the review was that, the beneficial effects, which were observed in the initial 6 months following the intervention, did not last during the maintenance phase in many studies. This phenomenon was observed for LDL, HDL and other metabolic parameters.

6. Conclusion

1. BMI were significantly lesser in the intervention group at 6-month period following the intervention. The mean BMI of subjects in control group was 30.91 ± 3.12, and in intervention group it was 27.24 ± 3.14. (P value <0.001).
2. The mean HbA1c (5.82 ± 0.31 Vs 5.14 ± 0.35. P value <0.001) were significantly lower in the intervention group, as compared to control group, at the end of 6 months follow up period.

3. The mean Triglycerides (157.95 ± 14.25 vs 149.37 ± 11.16, P value <0.001) and VLDL (31.59 ± 2.85 Vs 29.87 ± 2.23, P value <0.001) were lower and the mean HDL was higher (42.58 ± 7.17 Vs 45.87 ± 7.05, P value 0.010) among the intervention group, at the end of 6^{th} month follow up period.
4. Majority of the parameters, which have shown statistically significant improvement within intervention groups, have done so in the first two months following the initiation of the intervention, with no statistically significant change after that.
5. However, the improvement from the baseline value has persisted till the end of 6^{th} month follow up period.

7. Disclosure

This Manuscript is a part of my project entitled " Evaluation of the effect of structured exercise therapy on neurophysiological and cognitive functions of young adults with type 2 diabetes mellitus – A Randomized Controlled Trial"

8. Sources of funding

I am grateful to Indian Council of Medical Research for funding this project.

References

1. Shaw JE, Sicree RA, Zimmet PZ. Diabetes Atlas-Global estimates of the prevalence of diabetes for 2010 and 2030. *Diabetes Res Clin Pract*. 2010;87:4–14.
2. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: Estimates for the year 2000 and projections for 2030. *Diabetes Care*. 2004;27:1047–1053.
3. Astrup A, Finer N. Redefining type 2 diabetes:diabesity or obesity dependent diabetes. *Obesity Rev*. 2000;1:57–59.
4. Zimmet SPP. Fighting the 'diabesity' pandemic. *Lancet*. 2006;368(9548):1643.
5. Kamath A, Shivaprakash G, Adhikari P. Body mass index and waist circumference in type 2 diabetes mellitus patients attending a diabetes clinic. *Int J Biol Med Res*. 2011;2:636–638.
6. Unnikrishnan R, Anjana RM, Mohan V. Diabetes in South Asians: Is the phenotype different? *Diabetes*. 2014;63:53–55.
7. Geiss LS, Wang J, Cheng YJ. Prevalence and incidence trends for diagnosed diabetes among adults aged 20 to 79 years. *JAMA*. 1980;312:1218–1226.
8. Gostic CL. The crucial role of exercise and physical activity in weight management and functional improvement for seniors. *Clin Geriatr Med*. 2005;21:747–756.
9. Kuhle CL, Steffen MW, Anderson PJ. Effect of exercise on anthropometric measures and serum lipids in older individuals: a systematic review and meta-analysis. *BMJ Open*. 2014;4:5283–5283. Available from: 10.1136/bmjopen-2014-005283.Lastaccessedon12th.
10. Colberg RS, Sigal JR. Exercise and Type 2 Diabetes. The American College of Sports Medicine and the American Diabetes. *Diabetes Care*. 2010;33(12):147–167.
11. Nazni P, Vijayakumar TP, Angamuthu K. Effect of Exercise on BMI and Biochemical Profile of Selected Obese Diabetic Women. *J Exerc Sci Physiotherapy*. 2006;2:66–70.
12. American Diabetes Association Physical activity/exercise and diabetes. *Diabetes Care*. 2004;27(90001):14–15.
13. Castaneda C, Layne JE, Lgordon PLMO, Walsmith J, Foldvari M. A randomized controlled trial ofresistance exercise training to improveglycemic control in older adults with type 2 diabetes. *Diabetes care*. 2002;25(12):2335–2376.
14. Lipsy RJ. The National Cholesterol Education Program Adult Treatment Panel III guidelines. *J Manag Care Pharm*. 2003;9(1):2–5.
15. DeFronzo RS, Ferrannini E, Zimmet P, Alberti G. International Textbook of Diabetes Mellitus. . *J Clin ApplRes Educ*;.
16. Defronzo RA, Ferrannini E, Zimmet P, Alberti G. Wiley-Blackwell ; 2015,. Last accessed on12th.
17. Forouzanfar MH, Afshin A, Alexander LT, Anderson HR, Bhutta ZA, et al. GBD 2015 Risk Factors Collaborators. Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990-2015: A systematic analysis for the Global Burden of Disease Study. *Lancet*. 2015;388:1659–1724.
18. Cho NH, Shaw JE, Karuranga S, Huang Y, Fernandes JDDR, Ohlrogge AW. IDF Diabetes Atlas: Global estimates of diabetes prevalence for 2017 and projections for 2045. *Diabetes Res Clin Pract*. 2018;138:271–281.
19. Min HR, Ahn KW, Seok HJ, Lee HG, Park JH, GS. Effects of Aerobic Exercise vs. Resistance Training on Endothelial Function in Women with Type 2 Diabetes Mellitus. *Diabetes Metab J*. 2011;35(4):364–373.
20. Anjos D, Moreira BS, Kirkwood RN, Dias RC, Pereira DS, Pereira LSM. Effects of aerobic exercise on functional capacity, anthropometric measurements and inflammatory markers in diabetic elderly women. *J Bodyw Mov Ther*. 2017;21(3):509–516.
21. Kuhle CL, Steffen MW, Anderson PJ, Murad MH. Effect of exercise on anthropometric measures and serum lipids in older individuals: a systematic review and meta-analysis. *BMJ Open*. 2014;4(6):e005283.
22. Mshunqane NC, Kalk JK. Effects of an exercise programme on non-insulin dependant diabetes mellitus. *S Afr J Physiother*. 2004;60(4):26–30.
23. Kadoglou NP, Vrabas IS, Sailer N, Kapelouzou A, Fotiadis G, Noussios G. Exercise ameliorates serum MMP-9 and TIMP-2 levels in patients with type 2 diabetes. *Diabetes Metab*. 2010;36(2):144–151.
24. Choi KM, Han KA, Ahn HJ, Hwang SY, Hong HC, Choi HY. Effects of exercise on sRAGE levels and cardiometabolic risk factors in patients with type 2 diabetes: a randomized controlled trial. *J Clin Endocrinol Metab*. 2012;97(10):3751–3758.
25. Byrne H, Caulfield B, Vito GD, G. Effects of Self-directed Exercise Programmes on Individuals with Type 2 Diabetes Mellitus: A Systematic Review Evaluating Their Effect on HbA1c and Other Metabolic Outcomes, Physical Characteristics, Cardiorespiratory Fitness and Functional Outcomes. *Sports Med*. 2017;47(4):717–733.

Author biography

Harpreet Kour Assistant Professor

Shivaprasad Goudar Professor

V A Kothiwale Professor

Cite this article: Kour H, Goudar S, A Kothiwale V. Impact of lifestyle modifications on obesity and biochemical parameters at different time intervals in newly diagnosed patients with type 2 diabetes mellitus – A randomized controlled trial. *Indian J Clin Anat Physiol* 2019;6(3):279-286.