Assessment of the Lifestyle Intervention in Prevention of Type 2 Diabetes Mellitus in a Group of Egyptian Population

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Abstract: Back ground: The efficacy of lifestyle intervention in reducing the incidence of type T2DM has been established by the Diabetes Prevention Program and other studies. Our primary objective was to test the feasibility of integrating less intensive lifestyle intervention therapy into patient visits to improve weight loss and decrease the intensity of metabolic syndrome and pre-diabetes risk factors. **Methods:** 499 middle-aged, overweight and obese subjects; mean age, 47 years; mean body-mass index 38 kg/m^2 were screened from 9/2009 till 3/2011for the presence of prediabetes. We surveyed their characteristics of life style: eating and exercise habits, body mass index, waist line, resting blood pressure, OGTT plasma glucose, total cholesterol, triglyceride, HDL and LDL after a 12-hour fasting. After ruling out secondary obesity a tailored individual life-style was advised, which focused on dietary interventions (low calorie diet) and increased physical activity. An oral glucose-tolerance test was performed at the end for those at risk of diabetes. The mean duration of follow-up was one year. **Results:** The intervention group showed significant improvement in each intervention goal, with significant mean differences weight change (−8.58 kg, (*P*<0.000)). Also, there was an improvement in other markers for risk of progression to diabetes {BMI (*P*<0.000) and waist circumference (*P*<0.000)}. The magnitude of weight loss was strongly associated with improvements in glycemia, with significant differences in fasting glucose (*P*<0.000), and post load plasma glucose profiles 1-h (*P*<0.015) and 2-h (*P*<0.042), were seen. **Conclusions:** less intensive lifestyle intervention (diet, physical activity) produced beneficial changes in clinical and biochemical parameters in those who are at risk of T2DM. This type of intervention is a feasible option to prevent T2DM and should be implemented in the primary health care system.

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1. Introduction

Diabetes has been recognized as being a serious threat to health and to economic development ***(1).***

New figures indicate that the number of people living with diabetes is expected to rise from 366 million in 2011 to 552 million by 2030, if no urgent action is taken ***(2).*** The major part of this numerical increase will occur in developing countries **(3*).***

Egypt is a developing country that is facing the double burden of malnutrition ***(4).***The changed consumption patterns of the Egyptian population due to changes in socio-economic status and feeding habits, urbanization and globalization during the last two decades have led to increased prevalence of obesity with Type 2 diabetes mellitus (T2DM) parallel to it ***(4,5).***

In Egypt 10.4% of the adult population (aged 20 - 79 years) have diabetes. However, since Egypt has a relatively young population this is corrected to 11.4% when used to compare with other countries and has no National diabetes programme (NDP) implementation ***(2).***

Epidemiologic data suggest that T2DM results from an interaction between a genetic predisposition and lifestyle factors ***(6)*** and that, 9 out of 10 cases of T2DM could be attributed to habits and forms of modifiable behavior ***(7).***The main risk factors are obesity, sedentary lifestyle ***(8)*** and unbalanced diet ***(9).***

The National Service Framework for diabetes suggests that subjects at increased risk of developing T2DM should be advised and helped to reduce their risk of progression. The key lifestyle changes which shown to reduce the risk of progression are weight loss and increased physical activity ***(10).***

IDF in 2010 recommended that, all people at high risk of developing T2DM could be identified through opportunistic self-screening. Once identified, they should have their plasma glucose levels measured by a health professional to detect Impaired Fasting Glucose (IFG) or IGT, both of which indicate an increased risk of T2DM. Prevention efforts should target those at risk in order to delay or avoid the onset of T2DM ***(2).*** The Finnish diabetes prevention program one of the largest studies to address the effect of lifestyle changes through diet and exercise showed that, even short term period of lifestyle modification a have a long term beneficial effect in reducing the risk of developing T2DM***(11).***

Aim of the work

Our primary objective was to test the feasibility of integrating less intensive lifestyle intervention therapy into patient visits to improve weight loss and decrease the intensity of metabolic syndrome and pre-diabetes risk factors.

The secondary objective, was to validate the Finland risk assessment score (FINRISK) in a population-based, cross-sectional setting and to study its feasibility as a screening tool for undetected T2DM and other abnormalities in glucose metabolism in middle-aged subjects.

2.Subject and Methods

Subjects

A total of 499 obese patients(90 male and 409 female) were screened from 9/2009 till 3/2011 with mean duration follow up 1 year. Their mean age, 47 years; mean body-mass index 38 kg/m2 We surveyed their characteristics of life style: eating and exercise habits, body mass index, waist circumference, resting blood pressure, OGTT plasma glucose, total cholesterol, triglyceride, HDL and LDL after a 12-hour fasting. After ruling out secondary obesity a tailored individual life-style which focused on dietary interventions (low calorie diet) and increased physical activity.

Inclusion Criteria:

- Male and female patients their ages 40 to 60 years.
- Ability to provide written informed consent.
- Mentally stable and able to comply with the procedures of the study protocol.
- Able to fill out questionnaires.
- ***Has metabolic syndrome as defined by three or more of the five risk factors***
- Elevated blood pressure (BP) above 130 mm Hg systolic and/or 85 mm Hg diastolic or drug therapy for elevated blood pressure
- Elevated waist circumference (WC)above 35" (female) or above 40" (male)
- Reduced high-density lipoprotein (HDL) of below 40 mg/dl (male) or below 50 mg/dl (female) or drug therapy for reduced HDL
- Elevated triglycerides (TG) of 150 mg/dl or above or drug therapy for elevated TG

Exclusion Criteria:

- Has been diagnosed with diabetes
- Significant exercise-restricting disease
- ECG evidence of ischemic heart disease at rest.
- Poorly controlled hypertension
- Psychiatric disease or dementia
- Already on unusually restrictive diet
- Use of tobacco
- Pregnant women.
- Subjects with major illness such as cancer, hepatic or cardiac diseases.

Methods

1-Medical Assessments

Including family history of chronic non-communicable diseases, pattern of physical activity, symptoms covering various systems, general examination including blood pressure measurements.

a-Anthropometric Measurements

Anthropometric measurements were performed at the start of the study and after the candidate decrease at least 5% of initial weight. Body weight was measured with scale to the nearest 0.1 kg, with the subject wearing only light clothing. Height was measured to the nearest 0.5 cm with the subject standing on the floor without shoes with the back straight against the wall. BMI was calculated as the ratio of the weight and height squared (kg/m^2).

Waist circumference (waist) was measured with the subject in standing position at the level midway between the lowest rib and the iliac crest to the nearest 0.5 cm and hip circumference was measured as the maximum circumference over the buttocks to the nearest 0.5 cm. Waist-to-hip ratio (WHR) was computed as the ratio between waist and hip circumference.

b-Biochemical Measurements

OGTT and lipid profile were measured at baseline and at the end of the study period only OGTT was performed**.** Venous blood samples were drown into heparinized tubes and plasma was separated by centrifugation of blood samples at 3000 rpm for 10 minutes.

Plasma was used for:

Blood glucose, triglycerides, and total and HDL cholesterol were estimated by spectrophotometric assays on automated clinical chemistry analyzer Bio-Labo Diagnostic Kenza Biochemistry, while LDL cholesterol was calculated from primary measurements using the empirical formula of the Friedewald equation (12).

- **Determination of Glucose :**

The participant's undergone an oral glucose tolerance test (OGTT) in order to detect previously undiagnosed diabetes. They consume 75 g anhydrous glucose in 300 ml of water over 5 min. Another blood samples were taken 1h and 2 hrs later. Blood was collected into plain and fluoride Glucose was measured in fluoride plasma by an electrochemical glucose oxidase method

2-Dietary and Physical Activity Assessment.

Food Frequency Questionnaire and 24 hours recall were done, 24 hours recall method obtain accurate amounts of foods & beverages consumed by patients in the 24 hours preceding data collection. The data from the dietary recall were used to arrive at estimates of daily nutrient intake from standard recipes; using published food composition databases. Adequacy of the diet consumed was assessed by comparing the energy and nutrient intake of the individual with his recommended dietary allowances "RDA" using (FAO/WHO/UNU, 1985; FAO/WHO, 2000).

The routine physical activity pattern of the subjects was assessed using a questionnaire carried out at baseline and at the end of the intervention study period.

Lifestyle intervention

The aim of the meetings was to increase the participants' knowledge regarding the importance of diet, and physical activity in the prevention of T2DM**.**

Dietary intervention

All participants received face-to-face consultation sessions (from 30 min to 1 h) with the study nutritionist at the start and every month, individual lifestyle counseling, including a risk assessment based on age, sex, total, LDL and HDL cholesterol, systolic blood pressure, BMI, known pre diabetes and family predisposition.

The main goals of the lifestyle intervention were based upon available evidence on diabetes risk factors. They were weight reduction ≥5%, moderate intensity physical activity ≥30 min/day, dietary fat <30 proportion of total energy (E %), SFA<10 E%, and fiber ≥15 g/1,000 kcal.

Discussions were individualized, focusing on specific individual problems. Printed material was used to illustrate the message and to serve as a reminder at home. The dietary advice was based on 24 hour dietary recall and food frequency questionnaire (FFQ), which were completed every month. Nutrient intakes were calculated, and a summary of the results was given and explained to the subjects. Subjects were encouraged to make intermediate goals for themselves by thinking about practical things they could try to change (e.g., instead of an abstract goal such as "increase fiber intake," a practical goal would be "eat a slice of baladi bread and one serving of vegetable on every meal"). Weight was measured at every visit, and a weight chart was drawn. The participants were also encouraged to measure and record their weight at home on a regular basis. Recommended weight loss was not more than 0.5 to 1 kg per week.

Exercise intervention

The subjects were individually guided to increase their overall level of physical activity. This was done by the nutritionist during the dietary counseling sessions and highlighted by the study physicians at the monthly visits. Endurance exercise was recommended to increase aerobic capacity and cardio respiratory fitness.

Statistical Analysis

In this analysis, the following participants were excluded: pregnant women; participants with incomplete FFQ (>10% of items with missing responses), participants with missing covariates and those with known diabetes.

The data are presented as means ± SD. An independent *t* test was performed to ascertain whether significant differences existed between the anthropometric and biochemical parameters of the subjects.

Repeated-measures ANOVA, with group as a factor, were performed to assess the change over time in the anthropometric, biochemical parameters between the two groups. Repeated-measures ANOVA was then used to assess for significant differences between the various time points in the subjects of both groups independently. The significance level was set at $P < 0.05$.

3.Results

The baseline distribution of male and female cases based on FINRISK Criteria are shown in table (1).

There was a statistically significant difference observed after life style intervention (Diet and exercise) as regard all parameters that are associated with risk of progression to diabetes (weight, BMI and waist circumference) (P= 0.000), as well as improvements in glycemia, with significant differences in fasting plasma glucose (P= 0.000), post load plasma glucose profiles 1-h (P= 0.015), and 2-hrs (P= 0.042), were seen in table (2).

There was a difference in weight from base line to the end of study, which showed significant correlation with difference changes in the fasting plasma glucose **(**P=0.006) and 2-hrs plasma glucose OGTT (mg/dl) (P=0.031) but not with 1-h plasma glucose OGTT, (Table 3).

Table (1) Base line Distribution of male and female Cases Based on FINRISK Criteria

Variable	Males	Females	*p*
	№ 90 (19.2%)	№ 409 (80.8 %)	
Clinical Data			
Age Groups (years) %			
<45	41.1	35.4	0.583
45-<55	42.2	47.2	
55-<65	16.7	17.4	
>65	9	0	
History			
Family History of Diabetes %			
No Family History of Diabetes	41.1	41.2	0.387
First-degree relatives with diabetes	48.9	43.5	
Second-degree relatives with diabetes	10	15.3	
Previous high blood glucose	6.7	11.3	0.293
Blood Pressure %			
Blood pressure–lowering medication	20	24.8	0.409
Physical Activity %			
On daily basis ≥ 30 min/day	43.3	33.2	0.072
Not on daily basis	56.7	66.8	
Vegetables and fruits consumption %			
On daily basis	53.3	51.5	0.815
Not on daily basis	46.7	48.5	
Anthropometric Data	**Mean ± SD**	**Mean ± SD**	
BMI (kg/m^2)	35.09 ± 15.69	38.79 ± 5.56	**0.000 ***
Waist circumference (cm)	113.90 ± 9.43	112.28 ± 11.25	0.210
Weight (kg)	99.98 ± 13.20	95.45± 15.54	**0.005***
Blood pressure			
Systolic blood pressure (> 130 mmHg)	149.37±15.69	144.85 ± 10.74	0.110
Diastolic blood pressure (> 85 mmHg)	94.59 ± 17.45	90.78 ± 6.83	**0.021***
Laboratory Data			
Fasting plasma glucose (mg/dl)	99.68 ± 21.43	95.53 ±17.09	**0.050 ***
1-h plasma glucose OGTT (mg/dl)	155.38±41.21	141.73±37.72	**0.002***
2-hrs plasma glucose OGTT (mg/dl)	125±61±35.95	116.21±33.94	**0.020***

Table (2): Changes in Selected Clinical and Metabolic Variables from Base-Line to the End of Year 1 in the Subjects in the Intervention Group

Variable	Baseline data Mean ± SD	End of the study Mean ± SD	*P* value
Weight(kg)	98.0 ± 13.6	89.4 ± 13.2	**0.000***
Waist(cm)	113.4 ± 8.5	102.2 ± 7.6	**0.000***
BMI(kg/m^2)	38.5± 5.3	34.9± 5.1	**0.000***
Fasting plasma glucose (mg/dl)	117.6 ± 32.01	96.0 ± 16.4	**0.000***
1-h plasma glucose OGTT (mg/dl)	172.1 ± 40.7	154.1± 38.8	**0.015***
2-hrs plasma glucose OGTT (mg/dl)	169.1 ± 179.3	119.5 ± 27.6	**0.042***

$P > 0.05$ considered not significant $P \leq 0.05$ considered significant

Table (3) correlation between the Mean Difference of Weight from Base-Line to the End of Year 1 and the change in FPG, 1-h&2-h OGTT in the Subjects in the Intervention Group

Variable	Mean ± SD	r	*P* value
Difference in Weight(kg)	8.7 ± 5.9		
Difference Fasting plasma glucose (mg/dl)	20.7 ± 29.4	0.170	**0.006***
Difference 1-h plasma glucose OGTT (mg/dl)	18.3± 47.3	0.067	0.196
Difference 2-h plasma glucose OGTT (mg/dl)	25.3±54.2	0.341	**0.031***

$P > 0.05$ considered not significant; $P \leq 0.05$ considered significant

4.Discussion

In our study, the distribution of male and female cases based on the FINRISK criteria shows that there is no differences between the males and females as regard the mean age, waist, the personal history of previous high blood glucose, family history of diabetes, blood pressure lowering medications nor the daily basis of physical activity and fruit and vegetables intake.

As regard clinical data, the females had significantly higher BMI (38.79 ± 5.56 kg/m^2) than males (35.09 ± 15.69 kg/m^2) with (p<0.000), the higher body mass index (BMI) in females and the waist circumference (WC) in both sexes (females 112.28 ± 11.25 cm) & (males 113.90 ± 9.43cm) demonstrates the existence of visceral obesity, however the males had significantly higher mean blood glucose levels through the OGTT (FPG, 1hr-OGTT and 2hrs-OGTT), (P =0.050),(P =0.002) and (P =0.020) respectively **(Table 1)**.

When we evaluate the effect of the lifestyle on the prediabetes state which was our primary goal, we found a statistically significant difference after life style intervention (Diet and exercise) with significant mean differences weight change (8.7 ± 5.9 kg) (P=0.000) **(Tables 2&3)**, this change was associated with improvement in waist circumference and other markers for risk of progression to T2DM {BMI (P=0.000) and (P=0.000)} **(Table 2)**.

Our results show that, lifestyle-change programme significantly reduced abdominal circumference and weight and this in concordance with ***(10&13***).

This also seen in a study, with total of 93 subject with metabolic syndrome & prediabetes with BMI ≥ 25 kg/m^2. Average combined weight loss for both groups over the course of the 3-month intervention was 3.5 kg (p<0.001); 23.8%, and 52.2% of those who completed the program reached 7% and 5% weight loss ***(14)***.

The magnitude of weight loss was strongly associated with improvements in glycemia, with significant differences in fasting glucose (20.7 ± 29.4 mg/dl) (P=0.000), and post load plasma glucose profiles 1-h (18.3± 47.3mg/dl) (P=0.015) and 2-h (25.3±54.2mg/dl) (P=0.042) **(Table 2)** were seen.

The lost weight was significantly correlated with the change in fasting plasma glucose (P = 0.006) and post load plasma glucose profiles 2-hrs (P ≤0.031) but not with post load plasma glucose profiles 1-h (P = 0.196) (Table 3).

The significant improvement in plasma glucose with life style changes and weight reduction in concordance with a study that was conducted in the urban setting using the traditional diet with measuring OGTT, weight at baseline and end of 7th wk of traditional lifestyle **(15)**,and the Oslo Diet & Exercise Study (ODES) which founded significant reductions in fasting blood glucose, BMI and improving carbohydrate metabolism especially when both exercise and diet intervention were applied ***(16).***

Moderate weight loss (5% of body weight) can improve insulin action, decrease fasting plasma glucose concentrations, and reduce the need for diabetes medications. Moreover, improvement in fasting plasma glucose is directly related to the relative amount of weight lost**(17)**. The same data from obtained nearly from the Diabetes Prevention Program (DPP) that demonstrated that weight loss (7% of weight loss in the first year) and increased physical activity (150 min of brisk walking per week) reduced the 4-year incidence of type 2 diabetes by 58% in men and women with impaired glucose tolerance and this persist for at least 10 years. **(18)**.

The Finnish Diabetes Prevention Study, one of the largest diabetes prevention programme on 522 middle-aged, overweight men and women with IGT showed that, persons in the diet and exercise intervention group lost 3.5kg and this was associated with decreasing the risk of developing T2DM by 58% over a 3-year interval**,** and this was sustained over long term (***19).***

The Diabetes Prevention Program Research Group notice a similar reduction in the fasting plasma glucose values in after life style intervention and that was more effective in restoring normal post-load glucose values in those who had abnormal glucose levels ***(20***), moreover body weight loss and increased physical fitness were the most important determinants of improved glucose tolerance and insulin sensitivity, and the greater weight loss was associated with significantly greater decreases in fasting and plasma glucose values than lesser weight loss, and this was also associated with decrease in the 2-hrs plasma glucose concentration (14.4± 5.4 mg/dl) ***(21).***

The same reported in the SLIM study in which the lifestyle programme was effective in reducing the intake of total and saturated fat, increasing physical activity, reducing obesity and improving insulin sensitivity and glucose tolerance ***(22).***

In a Hindu randomized study on 1,253 person with IGT and/or IFG there is 83 % of the group reporting weight loss (between 2.5 kg to over 6 kg) and this was associated with marked improvement in glucose ***(*23*).***

This was also seen in a recent study on 81 participants (71 women, 10 men) with mean overall weight loss 5.1kg (P < 0.001); with significant decreases noted in fasting plasma glucose **(24).** The same results also seen in another study in which decreased weight (-7.1kg), BMI (-2.1 kg/m^2), and waist circumference (-5.9cm) after one year, strongly increased the chances of returning from prediabetes to normal glucose tolerance irrespective of initial BMI in older adults **(25)**,**(26)** the same observed in viscerally obese men after 1 year of life style intervention ***(27).***

So, lifestyle modification is a useful tool in preventing the onset of diabetes, and reducing the associated increased risk of morbidity and mortality that might otherwise overwhelm health care systems in developing countries ***(28).***

Findings of the previous studies indicate that the most successful interventions were combined individual dietary counseling with an increased physical activity. Another factors predicting success are weight loss achieved, duration and intensity of the intervention and dietary compliance ***(29).*** Individualized medical nutrition therapy seems to be an important factor in primary prevention of T2DM and to minimize associated risk. The effectiveness of the life style intervention strategy has been checking out by comparing it with treatment by antidiabetic drugs and placebo ***(30)***. It is nearly twice as effective as metformin therapy (31% reduction in incidence of diabetes) in preventing type 2 diabetes ***(20).***

Nevertheless, our data do indicate that a lifestyle intervention based on general recommendations, when strictly followed results in much larger changes in body weight and glucose tolerance. A considerably larger reduction in bodyweight and waist circumference was observed in those who were more adherents to both dietary intervention and physical activity. This increased waist loss is probably an important mediator of the improved glucose tolerance. Adding physical exercise to the medical nutritional therapy induced weight loss program is important because it improves weight maintenance in the long term ***(31).***

5. Conclusion

Less intensive lifestyle intervention (diet, physical activity) greatly improved clinical and biochemical parameters in those who are at risk of T2DM, and that, FINRISK score system is applicable in our population.

6. Recommendation

Lifestyle intervention is a relatively simple tool and seems to work well, and it is recommended for planning and implementing community-based diabetes prevention programs.

7. Strength and limitation

The strength of our study is that it is the first study to our knowledge in evaluating the effectiveness of life style modification on the blood glucose levels in prediabetics in Egypt.

The limitation is smoking and alcohol consumption are of value-laden behaviors and we did not include them in questionnaire.

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