



ROLE OF METABOLIC SYNDROME MANAGEMENT PROGRAM IN THE CONTROLLING OF TYPE 2 DIABETES MELLITUS

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ABSTRACT

The burden of type 2 diabetes mellitus (DM) and metabolic syndrome (MetS) continues to rise and constitute a real threat, especially in the developing world. Change in lifestyle is important to control and slow down the progress of MetS. This study was designed to evaluate the effectiveness of an educational lifestyle modification on controlling type 2 diabetic patients with MetS. A total of 107 type 2 diabetic patients having MetS were randomly assigned into two groups, intervention and usual care groups. The intervention group received clinical pharmacist education about type 2 diabetes, and risk factors of it, prescription medication and necessary lifestyle changes, while the usual care group has received the usual medical services. The primary outcome measure was glycemic control (HbA_{1c}), and the secondary measures included FBS (fasting blood sugar), waist circumference, systolic and diastolic blood pressure and complete lipid profile. Medication adherence was assessed using Morisky scale while summary of diabetes self-care activity scale (SDSCA) was used to assess the lifestyle modification. All measures were collected at baseline and after 3- month follow-up. Compared with baseline values, patients in the intervention group had a significant reduction of HbA_{1c} value while significant elevation of it in the usual care group. Comparing to the usual care group, the intervention group had significant improvements in the secondary outcome measures of FBS, waist circumference, BMI, systolic, diastolic blood pressure, triglycerides, VLDL, total cholesterol and atherogenic index. Clinical pharmacist Intervention had positive effect on Morisky scale and SDSCA in the intervention patients. Lifestyle intervention which included change in diet, exercise, and education showed significant benefit in reduction of HbA_{1c} level and a number of risk factors related to MetS.

Keywords:

INTRODUCTION

Type 2 DM is a heterogeneous group of disorders that in combination result in hyperglycemia. These disorders include β cell death, insulin resistance, excessive hepatic glucose release, and other hormonal deficiencies [1]. A majority of patients with type2 DM have a feature of the metabolic syndrome (MetS), also called syndrome X or the insulin resistance syndrome [2].

The term MetS (sometime termed insulin-resistant syndrome or cardio metabolic syndrome) refers to a clustering of risk factors that include abdominal obesity, dyslipidemia, hyperglycemia, and hypertension [3]. MetS is an important risk factor for cardiovascular disease (CVD), type 2 DM and all-cause mortality. therefore, MetS might be useful as practical tool to predict these two major

metabolic disorders. The underlying conditions that promote the development of MetS and DM are overweight and obesity, physical inactivity, and an atherogenic diet [4]. Ideally, management of the MetS should focus on its underlying cause. The mainstays of treatment are lifestyle interventions to address central obesity and insulin resistance [5]. Weight loss interventions based on caloric restriction, increased physical activity and behavior modification have been recommended by the National Health and Medical Research Council new obesity management guidelines [6].

The goals for type2 DM patients are to eliminate symptoms and to prevent, or at least slow, the development of complications. Microvascular (eye and kidney disease)

risk reduction is accomplished through control of glycemic and blood pressure [7]. Macrovascular (coronary, cerebrovascular, peripheral vascular) risk reduction, is through control of lipids and hypertension, smoking cessation, and aspirin therapy; and metabolic and neurologic risk reduction, through controlling of glycemia [8]. However, focus on glucose alone does not offer adequate treatment for patients with diabetes mellitus, treatment involves multiple goals (glycemia, lipids, blood pressure) [9].

The role of the pharmacist has been changing over the past two decades. The pharmacist is no longer just a supplier of medicines and a concocter of medicinal products, but also a team member involved in provision of health care whether in hospital, the community pharmacy, the industry, the laboratory, or academic organizations [10]. The primary purpose of this study is to evaluate the effectiveness of education action in promoting self-management of care, associated to diet, exercise, and blood glucose in controlling type 2DM patients having MetS. The second purpose is to study the effectiveness of this education program on the achievement of the control of metabolic syndrome and its influence on the control of type 2 DM. To evaluate these aims certain parameters were chosen as primary and secondary goal. HbA_{1c} were used as primary goal for determining diabetes control. Whereas triglyceride level, HDL, Blood pressure, waist circumference, and FBS were determined as secondary goal for follow up.

PATIENTS AND METHODS

This randomized controlled study was carried out from 5 October 2015 to 1 May 2016 at Layla Qasim Diabetic Center Erbil-Iraq.

Ethical consideration

The study was approved by the scientific and research committee of college of pharmacy, university of Mosul and health and safety board of Erbil directorate, Erbil-Iraq. More over; informed consent was obtained from all patients accepted to participate in the study.

Patients

One hundred and thirty diabetic patients (type 2 DM) were asked to participate in the study. One hundred and seven patients were involved in the study, the rest did not come to follow up for different causes.

The mean age \pm SD of the study patients were 55.5 \pm 7.2 years and ranged from 36 to 74 years. The patients were divided randomly into Intervention group (54 patients, 6 males and 48 female) and Usual care group (53 patients, 9 males and 44 female)

Inclusion and exclusion criteria

Inclusion criteria included Type 2 diabetic patients, attending diabetic center suffering from metabolic

syndrome. Patients were excluded from the study if they have other lipid- altering diseases like hepato-biliary disease, hypothyroidism, chronic kidney disease and nephrotic syndrome, alcohol consumption and women who were pregnant or using oral contraceptive pills. The data were collected in two stages:

First stage (baseline visit)

In this stage, the information of the patients participated were obtained from patients directly through interviews with them during visits in Layla Qasim diabetic center.

A health questionnaire forms were designed to record the patients information including demographic measures (name, age, gender, marital status, education, work, economic status), disease profiles including duration of diabetes, diabetic medication used by the patients, presences of hypertension, dyslipidemia and cardiovascular diseases, (duration of the diseases and their treatments) and family medical history. Beside that anthropometry measures (waist circumference, blood pressure, height and weight to calculate body mass index BMI) were recorded. Morisky Medication Adherence Scale (MMAS-8) 8item and Summary of diabetic self- care activities questionnaire (appendix III) were conducted. There after patients were submitted to determine their fasting plasma glucose, glycated hemoglobin (HbA_{1c}) and lipid profile (total cholesterol, LDL _cholesterol, HDL _cholesterol and, triglyceride) Atherogenic index(AI) and very low -density lipoprotein (VLDL) also were calculated. At this stage, patients were allocated randomly to intervention or usual care groups.

The patients in the intervention group were educated about type 2 diabetes, risks for and types of complications from diabetes, prescribed drug therapy, proper dosage, possible side effects, and the importance of medication adherence. The patients have emphasized lifestyle managements as- patients were encouraged to, change unhealthy dietary habits that adversely influence blood glucose, blood pressure, and lipid level. Perform regular physical activity that fits with their daily schedule and monitor and record their blood glucose levels.

Finally, direct contact and frequent telephone calls were made to each intervention patient to discuss and review the prescribed therapy, to emphasize the importance of adherence to the treatments. The patients in usual care group did not receive intervention or education on their diseases, medications, or necessary self-care activities from the clinical pharmacist, but they were left for the usual education by physician and health professional in medical center.

Second stage (after 3 months follow)

At this stage all patients were re-evaluated second time for the anthropometry measure (weight, height, waist circumference, and blood pressure). Scales (Morisky scale

and SDSCA) and all biochemical investigations were repeated at this stage for evaluating of clinical progress of the patients.

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 22). Chi square test of association was used to compare between proportions. When the expected count of more than 20% of the cells of the table was less than 5, Fisher's exact test was used. McNemar test was used to compare proportions of the same sample (before and after the intervention). For 3X3 tables, McNemar-Bowker test was used (also for same sample, before and after the intervention). Student's t test was used to compare means of the two study groups. Paired t test was used to compare readings before and after the intervention (of the same sample). A p value of ≤ 0.05 was considered statistically significant.

RESULTS

Effect of clinical pharmacist intervention on the anthropometry variable

Significant difference (decrease or increase) were detected between the results, before the intervention (baseline) and after the intervention (after 3month follow) for the majority of the variables, while in the usual care group, no significant differences were found between results at baseline visit and after 3 months follow for most of the anthropometry parameters (table 1).

Effect of clinical pharmacist intervention on biochemical variable in the studied groups

The results showed in table 2 that the clinical pharmacist education has given significant effect on some biochemical parameter in the intervention group as there were significant reductions in FBS level and HbA_{1C} in addition to cholesterol, VLDL, atherogenic index and TG have also significantly decreased. While in the usual care group HbA_{1C} level was significantly elevated.

Effect of clinical pharmacist intervention on SDSCA and Morisky scale

Table 3 shows that there were significant improvements in both studied scales, SDSCA and Morisky scales in the intervention group. No significant improvements were detected in the studied scales in the usual care group (at the end of the study).

Effect of clinical pharmacist intervention on the adherence level according to Morisky scale

Table 4 shows that the adherence to medications of intervention group(54patients), 40 (74.0%) patients was low and 11(20.4),3(5.6) patients was moderate and high respectively before the intervention. After the intervention, only 16 (29.6%)patients was low and 30(55.6), 8(14.8) patients was moderate and high respectively. In the usual care group, no significant differences in the adherence levels were detected between baseline and after 3 months follow ($p = 0.974$).

Effect of clinical pharmacist intervention on primary and secondary goal of the study

Effect of pharmacist intervention on HbA_{1C} level (primary goal of intervention)

The primary goal is to achieve controlled diabetes by making HbA_{1c} $\geq 7\%$. Table 5. shows significant reduction in the prevalence of uncontrolled diabetes (77.8% to 59.3%) in the intervention group ($p = 0.006$). On the contrary, in the usual care group, the prevalence was non-significantly increased ($p = 0.07$).

Effect of pharmacist intervention on the parameters of metabolic syndrome (secondary goal of intervention)

The controlled of metabolic syndrome have been calculated by measurement of parameters which was considered as secondary goal to be achieved in the study. In the intervention group, the proportion of patients with abnormal triglycerides reading decreased significantly after the intervention (from 68.5% to 51.9%). The same can be applied for uncontrolled hypertension, where the proportion of patients with abnormal blood pressure readings decreased from 72.2% to 42.6%. In the usual care group, no significant differences were detected between the readings at baseline and after 3 months follow (Table 6).

Table 1. Comparisons between the means of anthropometry parameters at base line and after three months follow in each of the studied groups.

Anthropometry parameters	Intervention		Usual care	
	At baseline	After 3- month	At baseline	After 3- month
Weight (Kg)	85.0 \pm 15.7	83.9 \pm 15.1*	82.7 \pm 14.4	82.7 \pm 14.5
BMI (Kg/m ²)	33.9 \pm 5.8	33.4 \pm 5.7*	33.0 \pm 5.6	33.0 \pm 5.7
Waist(cm)	113.0 \pm 9.9	109.0 \pm 9.8*	110.9 \pm 8.7	108.8 \pm 8.6*
SBP (mmHg)	145.8 \pm 21.7	129.9 \pm 12.0*	135.0 \pm 17.8	131.1 \pm 16.3
DBP mmHg	88.1 \pm 11.3	80.8 \pm 8.7*	83.4 \pm 9.6	82.5 \pm 8.7
Mean BP (mmHg)	107.4 \pm 12.7	97.2 \pm 8.7*	100.6 \pm 11.3	98.7 \pm 10.2

*Comparing to its baseline, the results expressed as mean and SD.

Table 2. Comparisons between the means of biochemical parameters at base line and after three months follow in each of the studied groups

Biochemical parameters	Intervention		Usual care	
	At baseline	After 3- month	At baseline	After 3 -month
FBS (mg/dl)	213.1±78.3	171.8±62.7*	213.7±90.8	191.8±71.4
HbA1c (%)	9.1±2.0	8.1±1.9*	8.3±1.6	8.9±1.8 *
Cholesterol (mg/dl)	196.2±57.0	176.7±42.0*	190.7±50.3	177.7±47.5
LDL (mg/dl)	106.6±38.6	97.9±32.9	108.1±42.4	97.9±37.1
HDL(mg/dl)	41.6±11.8	41.0±9.6	41.5±10.6	40.5±11.1
TG(mg/dl)	264.3±209.9	192.9±121.8*	230.0±190.6	207.1±131.5
Athero.Index	5.1±2.0	4.6±1.6*	4.9±1.9	4.7±1.8
VLDL (mg/dl)	52.9±42.0	38.6±24.4*	46.0±38.1	41.4±26.3

The results expressed as mean±SD.

Table 3. Comparisons between the means of summary of diabetic self-care activity and Morisky scale at base line and after three months follow in each of the studied groups.

	Intervention		Usual care	
	At baseline	After 3- month	At baseline	After 3 -month
S DSCA: General diet	2.3 ±1.7	3.6 ±1.9*	2.7 ±2.1	2.7 ±1.9
Specific diet	3.5 ±1.5	4.8 ±1.4*	4.0 ±1.6	4.1 ±1.6
Exercise	2.5 ±1.9	3.2 ±2.2*	2.9 ±2.5	2.9 ±2.3
Bl. sugar testing	1.9 ±2.4	2.2 ±2.6*	1.3 ±2.1	1.2 ±2.0*
Moriskey scale	3.8 ±2.0	2.0 ±1.4*	3.2 ±2.0	3.0 ±1.7

Table 4. Adherence to diabetes medications before and after the intervention, according to Morisky scale, in each of the studied groups.

Adherence	High		Moderate		Low		p
	No.	%	No.	%	No.	%	
Intervention group							
At baseline	3	5.6	11	20.4	40	74	0.000
After three months	8	14.8	30	55.6	16	29.6	
Usual care group							
At baseline	6	11.3	13	24.5	34	64.2	0.974
After three months	6	11.3	14	26.4	33	62.3	

The results expressed by number and percent (%).

Table 5. Prevalence of uncontrolled diabetes (assessed by HbA_{1c}) before and after the intervention in each of the studied groups.

	Intervention group			Usual care group		
	Prevalence of uncontrolled DM%			Prevalence of uncontrolled DM%		
	Baseline N %	After 3 months N%	P	Baseline N%	After 3 months N%	P
Diabetes control according to HbA _{1c} %	(42.01)77.8	(32.02)59.3	0.006	(39)73.6	(44.9)84.9	0.070

Table 6. Prevalence of the abnormal readings of the five parameters of metabolic syndrome before and after the intervention in each of the studied groups.

Parameters of metabolic syndrome	Intervention group		Usual care group	
	% of abnormal finding		% of abnormal finding	
	Baseline	After 3 months	Baseline	After 3 months
WC (cm)	100	96.3	96.2	96.2
TG (mg/dl)	68.5	51.9*	71.7	62.3
HDL (mg/dl)	74.1	81.5	75.5	81.1
FBS (mg/dl)	100	98.1	100	98.1
BP(mmHg)	72.2	42.6*	49.1	43.4

*WC=Waist circumference; TG =Triglycerides; HDL = High density lipo-protein cholesterol; FBS = Fasting blood sugar; BP = Blood pressure.

DISCUSSION

A clinical pharmacist intervention that consists of optimizing pharmacotherapy, individualized self-management education, adherence support, and regular direct and indirect contact resulted in significant improvement in HbA_{1c}, which is the primary outcome measure in this study. The present study found significant reduction of HbA_{1c} level in intervention group, while significant elevation of it in the usual care group. This improvement in HbA_{1c} was probably due to an improve in adherence to prescribed medication and lifestyle modifications. An important finding in the present study was that only 59.3% of patients in the intervention group have not achieved the ADA target goal for HbA_{1c} of less than 7% at the 3-month assessment, while 84.9% of patients in the usual care group did not achieve the target goal for HbA_{1c}. Corresponding data from the RCT by Al Mazroui indicated that 45.4% of patients in the intervention group and 30.3% in the control group achieved the ADA target at a 12-month follow-up assessment [11]. Sanghani found that each 1% increase in the level of HbA_{1c}, the absolute risk of CVD was increased by 1.18%, while each 1% decrease in HbA_{1c} levels was associated with a 37% reduction in micro-vascular complications and a 14% reduction in myocardial infarctions [12].

The present study indicated significant improvement in FBS values in patients who received pharmaceutical care intervention when compared with usual care patients over 3 months study period. This finding is consistent with findings of Jarab who reported a significant decrease in FPG in patients who received pharmaceutical care intervention at the end of a 6-month follow-up period [13].

Hypertension and type 2 DM are closely related to each other in clinical setting, apart from being a complication of type 2 DM, it is also a major risk factor for cardiovascular disease and a symptom of MetS [14]. The results of this study exposed that there were significant differences over time between the two groups with regard to blood pressure with significant improvement in systolic, diastolic and mean blood pressure in the intervention group. These results might be due to patient's education about the complications of DM, lifestyle behaviors as (healthy diet and exercise) and medication adherence.

In the current study, significant improvements were observed about body weight, waist circumference and BMI at the 3-month follow up. Weight loss was achieved by the education about reducing total calories and fat intake and by increasing physical activities. Weight loss has an important role in improving insulin sensitivity in liver and skeletal muscle and may also reduce pancreatic fat accumulation [15].

The results of this study can be supported by community-based study of Vita who reported that a lifestyle intervention reduced weight and better diet and physical activity at 12 months among participants at high risk of developing DM [16]. The result of this study is also in accordance with Chen, Yang and Sadiya who observed that life style intervention program was successful for BMI and weight management. This benefit was not only for contributing to weight loss and fat loss but also in improving the glycemic control in type 2 diabetic patients [17-19].

Waist circumference is a strong predictor of an increased risk for a host of diseases, such as dyslipidemia, diabetes, and hypertension independent of BMI [20]. The present study showed significant reduction in waist circumference in both study groups at 3 months follow, this result is consistent with finding of Gerstel who found that waist circumference reduced significantly in both intervention and control groups [21].

The present study found significant improvement in the intervention group in measures of lipid profile as triglyceride, total cholesterol, atherogenic index and VLDL. The lipid abnormalities are prevalent in DM because insulin resistance or deficiency affects key enzymes and pathways in lipid metabolism [22]. Lowers total cholesterol, triglycerides and VLDL-C may help to achieve atherogenic cholesterol goals. Regular exercise can limit the accumulation of adipose tissue and improve the blood lipid profile of patients [23-25].

Metabolic syndrome accelerates both macro vascular and microvascular complications such as diabetic nephropathy and hypertension [26]. It is important for the focus of treatment of the MetS to be on lifestyle changes, especially increased physical activity and weight reduction [26]. Some of parameters like (waist circumference, HDL-c and FPG) which contributed to the diagnosis of MetS have not been significantly changed where as systolic, diastolic blood pressure and triglyceride parameters were significantly changed. While a study of Jahangiry reported significant changes in all parameters of MetS. The study by O'Neill and O'driscoll [27, 28] indicated an additive effect of each MetS component leading to produce MetS which increased risk of CVD and T2DM. Therefore, a decrease in one or two of the components of MetS could potentially reduce the risk of CVD and T2DM.

Patients who received the clinical pharmacy intervention in the present study demonstrated significantly better self-reported medication adherence compared with the usual care group patients, because educating patients about medication adherence resulted in improvements in medication adherence and glycaemic control. Corresponding studies by Samu reported significant improvement in medication adherence [29].

In the present study, summary of diabetic self-care activities (SDSCA) has been used to assess self-care activities of diabetic patients in relation to pharmacist intervention in the studied groups. The significant improvement in dietary dominoes in intervention patients at the end of the present study is consistent with findings from earlier research. Jarab reported that clinical pharmacists were effective in increasing the number of days per week that patients consumed engaging in healthy diet and diabetes self-care activities intervention based on a lifestyle modification by pharmacists can play a role in improving glycemic control of patients with type 2DM, as evaluated by HbA_{1c}.

Patients who received the clinical pharmacy intervention in the present study had significantly better self-reported physical activity than did patients in the usual care. Significant improvement in diet and physical activities dominoes is related to the intervention of patients about the healthy diet and the importance of exercise in improving type 2 DM

The lifestyle modifications of the approval of a healthy dietary pattern together with increase physical activity and regular exercise are important in reducing the risk of type 2 diabetes [30]. Several studies have assessed the effects of exercise training on glycemic control. Exercise is generally recommended for people with type 2 diabetes. Physical activities on a regular basis improves metabolic, blood lipid profile control and quality of life. Additionally, have shown preventive effects of physical activity in individuals with type 2DM in lowering the risk of cardiovascular disease and premature death [31,32].

The present study found significant improvement in SMBG in the intervention patients could be attributed to

the intervention by the clinical pharmacist about the blood glucose values indicative of hyperglycemia and hypoglycemia and about how to respond appropriately to these results.

Self-management of diabetes remains the cornerstone of diabetes care. An overall self-management method would be greatly positive to people with diabetes as well as to their families. SMBG is an essential component of effective therapy, that more regular self-monitoring of blood glucose levels is related with clinically and statistically better glycemic control regardless of diabetes type or therapy [33].

CONCLUSIONS

The present study found that a clinical pharmacy education program for patients with type 2 diabetes, have improved biomarker parameters, including HbA_{1c}, blood pressure and lipid profile, in addition to self-reported medication adherence and self-care activities. The consistent education about controlling risk factors of MetS has led to good glycemic control in type 2 diabetic patients. Future prolong studies of more than 12 weeks length are needed to study the maintenance of positive outcome on risk factor of type 2 DM as a result of lifestyle intervention.

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Nil

CONFLICT OF INTEREST

No interest

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