EXPLORING THE ROLE OF CLINICAL PHARMACIST INTERVENTION ON THE OUTCOMES OF PATIENTS WITH TYPE 2 DIABETES MELLITUS

Zheen Aorahman Ahmed [a], Zhwan Azad Abdallah [b], and Tavga Ahmed Aziz [b]

Submitted: 6/2/2020; Accepted: 1/12/2020; Published: 21/12/2020

ABSTRACT

Background

Diabetes mellitus has been commonly identified as a metabolic disorder characterized by hyperglycemia that occurs as a result of insulin secretion deficiencies, insulin action, or both. It is the fourth largest cause of death, researches aimed to define and compare the views of pharmacists of type 2 diabetes mellitus about causes and methods that improves quality of life and consistency to medication. In order to obtain better therapeutic outcomes by decreasing medicine-related issues it needs to work closely with the patient in implementing and tracking therapeutic plans.

Objectives

The present study was aimed to evaluate the role of clinical pharmacist interventions in improving the outcome of patients with type 2 diabetes mellitus**.**

Methods

The study was conducted between December 2018 to April 2019 at the Center of Diabetes and Endocrine disease, Directory of Health/ Sulaimani city. One hundred and twenty patients with type 2 diabetes mellitus were randomly divided into two groups: Conventional group that received the usual care and interventional group that received the clinical pharmacist intervention including patient education on life style modification and general guidance on drug therapy that aimed to improve patients' quality of life and decrease the cost on the diabetic center. Blood sample collected from each patient at zero time and after 90 days of measuring fasting blood glucose, glycosylated hemoglobin and insulin level.

Results

Clinical pharmacist intervention resulted in a significant decrease in body weight, waist circumference and body mass index with no significant change in visceral adiposity index after three months intervention compared to baseline value. It also significantly decreased fasting blood glucose, glycosylated hemoglobin, serum insulin level, and insulin resistance when compared with the baseline value and the conventional group at the end of the study. The interventional group showed reduction in frequency of negative impacts of diabetes mellitus when compared to the baseline value and the conventional group, the intervention also resulted in decreased the cost on the diabetic center.

Conclusion

The implementation of diabetic self-care intervention by the pharmacist was effective in improving glycemic status, and body weight. The intervention also caused reduction in frequency of negative impacts of diabetes mellitus eventually initiated reduction in the overall healthcare cost of diabetic patients compared to patients received usual care.

Keywords: *Type 2 Diabetes mellitus; Clinical pharmacist intervention; Glycemic status; Quality of life; Cost-effectiveness.*

[a] Department of Pharmacology & Toxicolog, College of Pharmacy, University of Sulaimani, Kurdistan Region, Iraq.
[b] Department of Clinical Pharmacy, College of Pharmacy, University of Sulaimani, Kurdistan Region, Iraq.
Correspondence: zheen.ahmed@univsul.edu.iq

https://doi.org/10.17656/jsmc.10280

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease that affects the health directly and associated with life threatening complications [1]. The disease characterized by a chronic hyperglycemic condition as a consequence of inadequate action of insulin[2]. The majority of patients with T2DM have a combination of risk factors, including high level of triglycerides (TG), low levels of high density lipoprotein (HDL), abdominal obesity, and high blood pressure [3]. Diabetes may develop long-term complications including macro and microvascular complications. Macrovascular complications such as cerebrovascular disease, peripheral vascular disease and ischemic heart disease accounts for the majority of patient morbidity and mortality, and microvascular complications such as retinopathy, nephropathy and neuropathies, which are more common causes of losing vision, renal impairment and lower limb amputations [4]. Many disease management strategies have been developed and implemented in various clinical settings around the world, taking into account the complications of T2DM and its high prevalence. Lifestyle changes and proper pharmacological therapy are the main means of improving disease management in diabetic patients, both of which require significant patient cooperation and participation [5].

In order to achieve better glycemic and metabolic control in diabetics; pharmacists should be involved in providing pharmaceutical care to improve the quality of life of the patients and to minimize the complications of the disease [6], this involves working faithfully with the patient through contributing in designing the proper therapeutic plans including drug monitoring and patient education to achieve better therapeutic results via minimizing medication related problems [7]. Self-management is an important component of the management of diabetes and a duty of the patient. Self-management of chronic conditions has been defined as: "The ability of the individual to manage the symptoms, treatment, physical and psychosocial consequences, and changes in the lifestyle inherent in chronic living conditions. The capacity to monitor one's situation and to respond to the cognitive, behavioral and emotional reactions needed for maintaining a good quality of life is part of efficient self-management [8].

Pharmacists are playing a remarkable role in providing pharmaceutical care in the developed countries [9]. The concept of clinical pharmacy is well known in developing countries, but the application of clinical pharmacy practice is still at embryonic stage [10], however, it is broadly believed that pharmacists can make a great influence on the establishment of the primary health care, especially in developing countries [9]. Accordingly, the present study was aimed to evaluate the role of clinical pharmacist intervention in improving the outcome of patients with T2DM.

Aim of study

To show the role of clinical pharmacist interventions in improving quality of life through providing pharmaceutical care, improving in clinical outcomes and reducing cost required for disease controlling.

METHODOLOGY

Ethical approval

The study protocol was approved by the Ethical Committee of the college of Medicine/University of Sulaimani, with registration number (8)-28 of April 2018 and carried out in accordance with the principles of the Declaration of Helsinki as revised in 2000; all patients gave informed consent.

Patients Selection and Randomization

The study was conducted between December 2018 to April 2019 at the Center for Diabetes and Endocrine disease, Directory of Health/ Sulaimani city. The patients were recruited from public hospitals or private clinics after diagnosis according to the selection criteria. One hundred and fifty patients were screened for eligibility. Only 120 patients met the inclusion criteria and enrolled randomly in the study (Figure 1).

The inclusion criteria were choosing patients of both sexes with age ranging (adult patient to 65 years) diagnosed as having (T2DM) and their glycemic status was not controlled by the currently used medications. The exclusion criteria were pregnant women and patients with type 1 diabetes mellitus (T1DM). After taking the demographic data, the patients were randomly allocated into two groups:

The conventional group included 60 patients received usual care and the intervention group whom been intervened by the pharmacist for three successive months. The intervention included interviewing each patient to evaluate the diabetes related quality of life. They also received diabetic medication counseling by the pharmacist which included reviewing their medications. Written educational instructions on dietary regulation, exercise and lifestyle modifications

have been provided to each patient. The patients had been advised to achieve and maintain their ideal body weights by dietary modifications. The reforms included lowering fat intake, raising the intake of high-fiber carbohydrates, reducing the intake of refined sugars and salts, decreasing alcohol consumption, equally spaced meals (4–5 hours apart). The intervention also included recommendation about doing regular exercise to decrease body weight, improve glycemic status and boost body sensitivity to insulin [11].

In the intervention group, participants were recommended to undergo regular annual eye exams to ensure that diabetic eye diseases are identified before causing permanent vision loss, control blood pressure within normal limits and avoid the risk factors such as smoking and alcoholism that increase blood pressure [12, 13]. They also trained to protect their feet in order to prevent gangrene. Another part of the intervention was concerned with general guidance on drug therapy as follow: (a) promptly taking the dose if missed, unless it is almost time to take the next dose, (b) avoiding doubling the dose, (c) avoiding cigarettes, (d) recognizing that medication relieves symptoms but does not cure hyperglycemia; (e) wearing or bearing medical diabetes documentation and (f) avoiding all medicinal items, including over - the-counter medicinal products, without medical authorization [14].The intervention also extended to patient education about their medications including giving information on the adverse reactions, management of hypoglycemia, correct use of insulin injections and suggesting increasing the dose of the oral hypoglycemic agents to the physician depending on the laboratory tests.

Data collection

A structured questionnaire was used to collect patients' demographic characteristics, co-morbid disease, and medications history, brief clinical inventory QOL-15 questionnaire [15] was used to assess the patient's quality of life. A structured questionnaire was used for cost-effectiveness [16]. Blood sample collected from each patient at zero time and after 90 days for measuring fasting blood glucose (FBG), HbA1c and insulin levels.

Statistical Analysis

Data were analyzed using the statistical package for social sciences version 17 (released 2008; SPSS Inc., Chicago, IL, USA). Results were presented in tabular form. Categorical variables were presented as frequency and percentages chi square (post –hoc analysis) test used to obtain P value .Continuous variables were presented as mean ± standard deviation, two sample student T-test used to obtain P value. P value ≤ 0.05 was considered statistically significant.

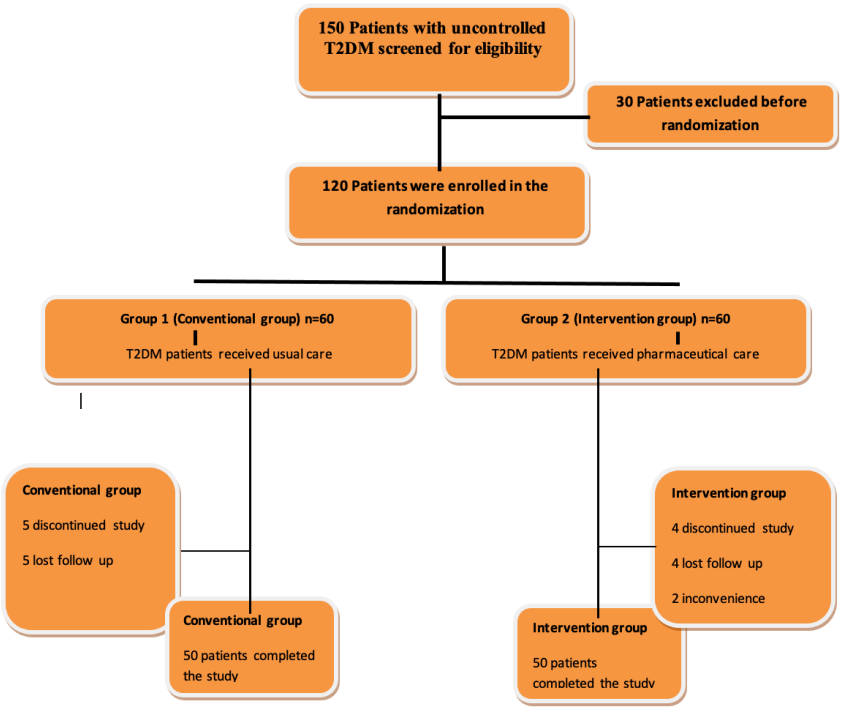

Figure 1. Flowchart of the study design.

RESULTS

The demographic characteristic of the study sample showed no significant differences regarding the gender, smoking, family history, age, duration of DM and presence of other concomitant illnesses (P> 0.05) (Table 1).

Role of clinical pharmacist intervention on body weight, waist circumference (WC), body mass index (BMI) and visceral adiposity index (VAI)

Clinical pharmacist intervention resulted in a significant decrease in body weight, WC and BMI with no significant change in VAI after three months intervention compared to baseline value. Regarding the conventional group, after three months of usual care there was a significant increase in the weight of the patients with significant decrease in the WC, but no significant differences were observed in BMI and VAI when compared to the baseline values. The differences between both groups were also non-significant (Table 2).

Role of clinical pharmacist intervention on glycemic status

The study revealed a significant decrease in the levels of FBG, HbA1c, insulin and insulin resistance (HOMA-IR) in the group that received clinical pharmacist intervention for 90 days compared with baseline values and with the conventional group. While a significant increase was noticed in the levels of the aforementioned parameters in the conventional group after three months of usual care compared with the baseline values (Table 3).

Role of clinical pharmacist intervention on patient's quality of life

According to brief clinical inventory QOL-15 questionnaire, patients quality of life include satisfaction with the treatment of DM and frequency of negative impacts of DM , regarding patients satisfaction with the diabetes treatment no statistically significant change found regarding interventional group when compare to baseline and conventional group, but in frequency of negative impact of DM this study shows significant improvement in intervention group compared to baseline but no significant change compare to conventional group at the end of the study (Table 4).

Role of clinical pharmacist intervention on cost effectiveness

Clinical Pharmacist intervention greatly contributed in significant decreasing of the cost regarding the number of medications used by the patients (p-value= 0.007), hospital admission (p-value= 0.0002), and medical procedures (p-value= 0.0002) compared to conventional after 90 days (Table 5).

Table 1. Demographic characteristics of diabetic patients.

		Conventional Group n=50 (%)	Interventional Group n=50 (%)	P value
Gender	Male	18 (36.0)	18 (36.0)	1
	Female	32 (64.0)	32 (64.0)	
Family history of T2DM	Yes	25 (50.0)	32 (64.0)	0.15
	No	25 (50.0)	18 (36.0)	
Smoking	Yes	3(6.0)	6 (12.0)	0.3
	No	47 (94.0)	44 (88.0)	
Age groups	35-44 years	7 (14.0)	4 (8.0)	
	45-54 years	18 (36.0)	25 (50.0)	0.3
	55-60 years	25 (50.0)	21 (42.0)	
Duration of T2DM	Less than 5 years	10 (20.0)	9 (18.0)	
	5-10 years	14 (28.0)	18 (36.0)	
	10-20 years	23 (46.0)	20 (40.0)	0.7
	20-30 years	2 (4.0)	2 (4.0)	
	More than 30 years	1(2.0)	1 (2.0)	
Concomitant illnesses	Hypertension	9 (18.0)	2 (4.0)	
	Hyperlipidemia	7 (14.0)	9 (18.0)	
	Hypertension & hyperlipidemia	20 (40.0)	18 (36.0)	0.1
	None of them	10 (20.0)	15 (30.0)	
	Others	4 (8.0)	6 (12.0)	

n; number of patients, T2DM; type two diabetes mellitus, %; percent categorical variable (percentages and proportions) were calculated .Chi-square test (post-hoc analysis) was used to obtain P value. P value was considered significant if it was less than 0.05

Table 2. Role of clinical pharmacist intervention on body weight, waist circumference, body mass index and visceral adiposity index

	Conventional group at zero time (mean ±STD)	Conventional group after 90 days (mean ±STD)	P value	Intervention group at zero time (mean ±STD)	Intervention group after 90 days (mean ±STD)	P value*	P value#
Weight (kg)	73± 13.69	80.9± 13.58	0.009	82.8±13.91	80±13.94	<0.001	0.98
WC (cm)	114.46±10.416	112.64±10.177	0.011	113.88± 9.65	109.3± 9.592	<0.001	0.094
BMI (kg/ m²)	31.53±4.799	32.08± 4.789	0.098	32.37± 5.924	31.77±5.965	0.003	0.77
VAI	8.266±5.451	9.245±7.072	0.218	7.452±7.157	7.742±4.425	0.583	0.068

STD; standard deviation, WC; waist circumference, BMI; body mass index, VAI; visceral adiposity index, kg; kilogram, cm; centimeter, m²; meter square

P value: refers to the level of significance between zero time and 90 days within conventional group

P value*: refers to the level of significance between zero time and 90 days within interventional group

P value#: refers to the level of significance between 90 days of conventional group and 90 days of intervention group

The results expressed as Mean± SD to describe continuous variables. P value was obtained for the continuous variable using T- independent two sample student T test.

Table 3. Role of clinical pharmacist intervention on glycemic status.

	Conventional Group at zero time (mean±STD)	Conventional Group after 90 days (mean±STD)	P value	Intervention Group at zero time (mean±STD)	Intervention Group after 90 days (mean±STD)	P value*	P value#
FBG (mg/dL)	201.94±78.9	224.36±85.16	0.084	237.94±93.272	172.38±62.1	<0.001	0.0007
HbA1c %	9.86±1.761	10.13±1.895	0.066	10.7±2	8.97±1.757	<0.001	0.0018
Insulin level (µIU/ml)	30.614±41.17	42.14±46.79	0.034	39.673±47.84	28.74±36.77	0.001	0.114
HOMA-IR	15.3±22.74	24.57±38.803	0.06	20.78±23.21	11.09±12.737	<0.001	0.021

STD; standard deviation, FBG; fasting blood glucose, HbA1c; glycosylated hemoglobin, HOMAIR; homeostatic model of insulin resistance, mg; milligram, dL; deciliter, µIU; international unit, ml; milliliter, %; percent

P value: refers to the level of significance between zero time and 90 days within conventional group

P value*: refers to the level of significance between zero time and 90 days within intervention group

P value#: refers to the level of significance between 90 days of conventional group one and 90 days of intervention group

The results expressed as Mean± SD to describe continuous variables. P-value was obtained for the continuous variable using T- independent two sample student T test

Table 4. Role of clinical pharmacist intervention on diabetes related quality of life

		Conventional Group (n=50)			Interventional group (n=50)			
		Zero time n=50 (%)	After 90 days n=50 (%)	P value	Zero time n=50 (%)	After 90 days n=50 (%)	P value*	P value#
Patient Satisfaction with treatment	Very satisfied	30(60.0)	33(66.0)	0.5	26(52.0)	21(42.0)	0.3	0.01
	Moderately satisfied	6(12.0)	10(20.0)	0.2	11(22.0)	11(22.0)	1.0	0.8
	Very dissatisfied	14(28.0)	7(14.0)	0.8	13(26.0)	18(36.0)	0.2	0.01
Frequency of negative impacts of DM	Never	32(64.0)	29(58.0)	0.5	19(38.0)	34(68.0)	0.002	0.3
	Sometimes	8(16.0)	3(6.0)	0.1	6(12.0)	5(10.0)	0.7	0.4
	All the time	10(20.0)	18(36.0)	0.07	25(50.0)	11(22.0)	0.003	0.1

n; number of patient, %; percent . P value: refers to the level of significance between zero time and 90 days within conventional group

P value*: refers to the level of significance between zero time and 90 days within interventional group

P value#: refers to the level of significance between 90 days of conventional group and 90 days of intervention group

Categorical variable (percentages and proportions) were calculated chi-square test (post-hoc analysis) was used to obtain P value. P value was considered significant if it was less than 0.05.

Table 5. Role of clinical pharmacist intervention on cost effectiveness

		Conventional group (n=50)			Interventional Group t (n=50)			
		Zero time n=50 (%)	After 90 days n=50 (%)	P value	Zero time n=50 (%)	After 90 days n=50 (%)	P value*	P value#
Current treatments	1+2	1(2.0)	2(4.0)	0.5	5(10.0)	11(22.0)	0.1	0.007
	1+2+3	49(98.0)	48(96.0)	0.5	45(90.0)	39(78.0)	0.1	0.007
Days of hospital admission within past 3 months	None of the time	24(48.0)	32(64.0)	0.1	23(46.0)	47(94.0)	0.0001	0.0002
	More than1 day	26(52.0)	18(36.0)	0.1	27(54.0)	3(6.0)	0.0001	0.0002
Number of medical producers within past 3 months	No procedure	26(52.0)	32(64.0)	0.2	32(64.0)	47(94.0)	0.0002	0.0002
	More than 1 procedure	24(48.0)	18(36.0)	0.2	18(36.0)	3(6.0)	0.0002	0.0002

1; metformin, 2; insulin and 3; other oral hypoglycemic treatments, n; number of patients, %; percent

P value: refers to the level of significance between zero time and 90 days within conventional group

P value*: refers to the level of significance between zero time and 90 days of intervention group

P value#: refers to the level of significance between 90 days of conventional group and 90 days of intervention group

Categorical variable rates and proportions were calculated chi-square test (post-hoc analysis) was used to obtain P value. P value was considered significant if it was less than 0.05.

DISCUSSION

To date, obesity is not well addressed as a disease contributing in many chronic diseases. The establishment of strategies aimed to help obese to loss weigh is essential [17]. Pharmacist may play a pivotal role in this respect as shown in the current study, where significant decrease in body weight, WC and BMI was observed at the end of the study. Other study proved that pharmaceutical care successfully improved the outcome of patients with T2DM through weight reduction and enhanced glycemic status [17]. In the present study, the intervention group revealed significant attenuation in the glycemic parameters. Studies proved that too much abdominal fat predicts insulin resistance and associated metabolic abnormalities frequently referred to as metabolic syndrome [18].

Some studies revealed no significant difference between the intervention and the conventional groups regarding the clinical parameters [19] emerging the need for doing more studies to reassess the role of pharmacist intervention especially in the developing countries. The current study showed a significant improvement in the glycemic status after pharmaceutical intervention. We found a strong association between clinical pharmacist intervention and clinical diabetes management and this finding is in tune with other studies [20]. In the developed countries, pharmacists are playing a critical role in the management of chronic diseases via providing pharmaceutical care and advice for patients with diabetes mellitus in primary care [10]. Many studies shows that clinical pharmacist guided appropriate interventions were found to be effective in achieving better glycemic control and better quality of life in patients with diabetes mellitus. The intervention group showed an improvement in the quality of life score also in present study patients self-care score shows a good improvement due to clinical pharmacist intervention they were advised how to manage side effects of treatments including hypoglycemia, gastro intestinal disturbance, pain. Also patients in intervention educated to follow a healthy diet as a part of treatment plan while in conventional group patients shows no significant change regarding reduction infrequency of negative impacts of DM [21].

From the economic perspective, the pharmacist as a member of the medical team can greatly be involved in decreasing the cost of medications, hospital admissions and medical procedures (minor surgeries) that spend on diabetic patients, as clearly noticed in this study, the contribution of the clinical pharmacist in diabetes self-care interventions shown to be cost-effective and can considerably improve the outcomes of the diabetic patients and reduces the risk of complications [16].

In conclusion, the implementation of diabetic self-care intervention by the pharmacist was effective in improving glycemic status and body weight and improving in quality of life. The intervention also increased the proper use of medication by the patients that eventually initiates reduction in the overall healthcare cost of diabetic patients compared to patients receive usual care.

Acknowledgement

The authors appreciate the College of pharmacy, University of Sulaimani for its support and providing facilities to this project.

Funding

This research did not receive any specific grants from funding agencies in the public, commercial, or not-for profit sector.

Conflicts of interest

The authors declares that there is no conflict of interest

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