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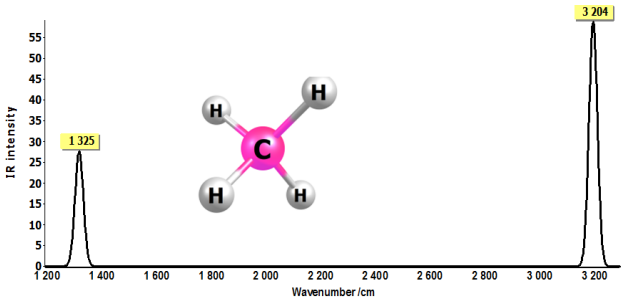

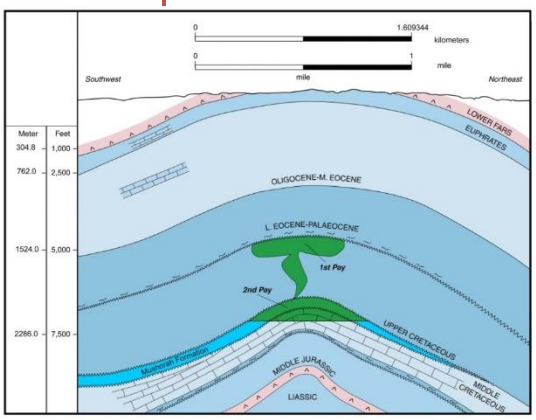

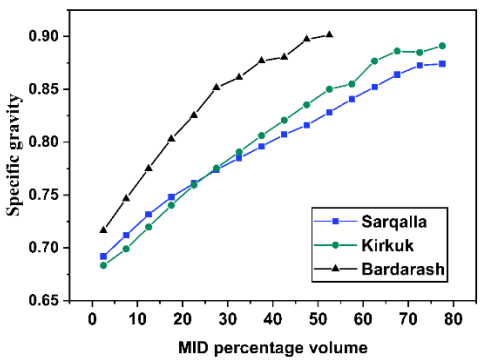

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Relationship between Medication Adherence and the Glycemic Control in Type 2 Diabetic Patients in Sulaimaniyah City, Kurdistan Region, Iraq

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Abstract

Background: Type 2 diabetes mellitus (T2DM) implies the highest incidence of diabetic cases. T2DM is related to metabolic ailments in the pancreas, kidneys, liver, and intestines. **Objective:** To determine the impact of adherence to antidiabetic medication (ADMs) on glycemic control in T2DM patients. **Methods:** This quasi-experimental study enrolled 245 participants (119 intervention patients and 126 non-intervention patients) with T2DM in the Diabetes and Endocrine Center, Sulaimaniyah, Iraq, from January to August 2021. ADMs used the Morisky Medication Adherence Scale Item 8 (MMAS-8). Also, fasting blood glucose (FBG) and glycosylated hemoglobin (HbA1c %) were checked to assess glycemic control among the participants. **Results:** The counseling program potentially improved ADMs as the rate of medium adherence increased significantly from 5.0% to 31.9% ($p<0.001$), with a significant improvement in glycemic control in the intervention group from 13.9% (before the intervention) to 21.8% (after the intervention) ($p=0.039$). However, there was no significant difference between ADMs and glycemic control ($p>0.999$). **Conclusion:** Patients' education and medication counseling significantly improved ADMs and glycemic control in people with T2DM.

Introduction

Diabetes mellitus (DM) is chronic hyperglycemia characterized by impaired carbohydrates, lipid, and protein metabolism due to complete or partial inability of insulin secretion or insulin effect. DM has become a global burden due to its high prevalence, growth rate, and long-lasting related complications (1). The International Diabetes Federation (IDF) reported that 463 million people aged 20-79 years are living with diabetes, which might increase to 700 million by 2045. In addition, diabetes is among the top ten leading causes of mortality annually that reached contagion scopes in the world (2,3).

The majority of individuals with T2DM are without appropriate treatment, which might result in significant mortality and morbidity (4). T2DM accounting for 90 to 95% of all cases of diabetes due to the severe metabolic disorders in vital body organs, which results in abnormalities including vascular rigidity,

nephropathy and retinopathy, and peripheral neuropathy (5). It has been demonstrated that optimal glycemic control is fundamental in the management of diabetes. However, some patients could control their hyperglycemia by consuming a healthy diet and regular physical activity, while others might need treatment for control and management (6).

There is a tremendous development and attempt in medical sciences to find the best therapy and management procedure for DM, but it is still incurable. Presently, insulin is a unique remedy for patients with T1DM. In contrast, for T2DM patients, various oral glycemic control medications are offered that need to be engaged lifelong to control the blood glucose level to its normal range. Therefore, observing glycemic amounts is very crucial. However, patients with DM are predictable to obey the treatment and low ADMs result in a high risk of impediments (7).

The American Diabetes Association (ADA) recommends using HbA1c to diagnose and monitor diabetes rather than FBG levels. HbA1c is a long-term glycemic control metric that can reflect 2-3 months of glycemic history. HbA1c levels in controlled diabetics should be less than 6.5%, and studies show that diabetic complications are manageable if the HbA1c level is <6.5%, and levels beyond 6.5% are uncontrollable (8).

Adequate and regular ADMs to the therapeutic regimen are essential and needed to attain the top conceivable treatment-related consequences. At the same time, poor ADMs is an extensive matter among patients with T2DM worldwide (9). Thus, this study aims to find the relationships between ADMs in T2DM patients and their glycemic control.

Materials and Methods

Patients and study setting

This quasi-experimental study was conducted on 245 patients (119 interventions and 126 non-interventions) with T2DM who visited the Diabetes and Endocrine Center, Sulaimaniyah, Iraq, from January to August 2021.

Sampling and sample size

The non-probability (purposive) with convenience sampling technique was performed, and two independent researchers collected data using the RaoSoft sample size calculator to determine the sample size. The criterion to split subjects into two groups was based on self-selection. The participants who chose to attend the program were enrolled in the intervention group. Other subjects who did not want to participate in the counseling program were in the control group. The patients in the intervention group were given appointments, including the date, time, and setting where the program was implemented. The program consisted of five sessions, lasting one and a half hours per week. Each session was about a particular topic: knowledge about DM, adherence to lifestyle and medication, medication storage, and drug administration.

Data collection and Instruments of the study

A specific and well-designed ADMs questionnaire was developed to assess adherence behaviors among participants. The questionnaire comprises sociodemographic characteristics, medical information, lifestyle assessment, and adherence factors using the Morisky Scale item-8 (MMAS-8) to measure obstacles and attitudes related to ADMs. MMAS-8 was applied after its translation into the Kurdish language, composed of eight questions with good validity and internal reliability. Response categories were yes/no for each question, with a dichotomous response and a 5-point Likert response for the last question. Based on the responses, each item was scored from 0 - 6=low, 6=medium; and 7- 8=high, and a total score was calculated (10). Then, the reliability of the Likert questionnaire was tested, and Cronbach's Alpha showed 0.68; then, the questions were directed to all the patients within the same order.

On the other hand, body mass index (BMI) was determined using weight (kg) and height (meter). Subsequently, the clinical parameters assessed the patients' glycemic control on the interview day. Then, 5.0

mL of blood was taken from each participant, and FBG (mg/dL) and HbA1c% were measured using COBAS-C11 and Toso-HP-723CX (Toso Automated Glycohemo-Analyzer).

Ethical consideration

The study plan and design were reviewed and evaluated by the Scientific Committee of the University of Sulaimani, College of Nursing; then, the ethical approval was guaranteed and approved by the Ethical Committee of the College of Medicine, University of Sulaimani, Iraq. Participants in the study were informed about the nature and objectives of the study. Patients were asked to provide verbal and written informed consent in Kurdish. They were also informed about the study's potential outcomes. Furthermore, patients' rights, confidentiality, and data protection are all considered. They were also given the option of withdrawing from the study.

Inclusion and exclusion criteria

Adult patients with T2DM who decided to contribute to the study were included regardless of age, gender, and severity of T2DM. Meanwhile, patients with Type 1 diabetes, gestational diabetes, organ failure, and mentally challenged patients were excluded.

Statistical Analysis

Collected data were analyzed using the Statistical Package for Social Sciences (SPSS, version 25), and a P-value of ≤ 0.05 was considered statistically significant.

Results

The mean age ± SD of the participants was 59.4 ± 9.0 years, the median was 60 years, and the age ranged from 40 to 79 years. No significant differences were detected in the age distribution or the mean age of the two study groups (p=0.219 and p=0.066, respectively). More than 2/3 of the patients (71.8%) were females, but there was no significant difference in the gender distribution among the study groups (p=0.667). The majority (77.1%) of the participants were married, without a significant difference between both groups (p=0.634). Around 2/3 of the individuals (64.1%) were homemakers, with no significant difference between the groups regarding occupation categories (p=0.459). The illiterate patients were higher in the non-intervention than in the intervention group (58.7% and 39.5%, respectively). The proportion of secondary school and college graduates was higher in the intervention than in the non-intervention group (p=0.019) (Table 1).

Before applying to the counselling program, only 14.4% in the intervention group compared with 12.2% in the control group were controlled (HbA1c≤6.5%) without a significant correlation between drug adherence and diabetes control (p>0.999) (Table 2).

After the administration of the counselling program, the rate of diabetic control in the intervention group increased to 21.8%, but in the non-intervention group, it remains low (13.1%). There was no significant difference between ADMs and diabetes control (p=0.391). In the non-intervention group, there was no significant association between drug adherence and diabetic control (p=0.156) (Table 3).

Table I. Socio-demographic characteristics of the study groups.

Variable	Intervention No. (%)	Non-intervention No. (%)	Total No. (%)	P-value
Age (Years)				
40-49	22 (18.5)	15 (11.9)	37 (15.1)	
50-59	42 (35.3)	37 (29.4)	79 (32.2)	
60-69	42 (35.3)	54 (42.9)	96 (39.2)	
70-79	13 (10.9)	20 (15.9)	33 (13.5)	0.219**
Mean ±SD	58.3±9.1	60.5±8.8	59.4±9.0	0.066†
Gender				
Male	32 (26.9)	37 (29.4)	69 (28.2)	
Female	87 (73.1)	89 (70.6)	176 (71.8)	0.667**
Marital status				
Single	2 (1.7)	5 (4.0)	7 (2.9)	
Married	93 (78.2)	96 (76.2)	189 (77.1)	
Widowed/ divorced or separated	24 (20.2)	25 (19.8)	49 (20.0)	0.634*
Educational level				
Illiterate	47 (39.5)	74 (58.7)	121 (49.4)	
Read and write	15 (12.6)	15 (11.9)	30 (12.2)	
Primary	29 (24.4)	23 (18.3)	52 (21.2)	
Secondary	21 (17.6)	12 (9.5)	33 (13.5)	
Higher education	7 (5.9)	2 (1.6)	9 (3.7)	0.019**
Occupation				
Employee (public)	18 (15.1)	14 (11.1)	32 (13.1)	
Free job	9 (7.6)	12 (9.5)	21 (8.6)	
Housewife	71 (59.7)	86 (68.3)	157 (64.1)	
Retired	19 (16.0)	13 (10.3)	32 (13.1)	
Jobless	2 (1.7)	1 (0.8)	3 (1.2)	0.459**
Total	119 (100.0)	126 (100.0)	245 (100.0)	

*Fisher's exact test, **Chi-square test, †Unpaired t-test

Table 2. Glycemic control by medication adherence before the implementing of the counseling program.

Drug adherence	Controlled diabetes No. (%)	Uncontrolled diabetes No. (%)	Total No. (%)	P-value
Intervention				
Low adherence	16 (14.3)	96 (85.7)	112 (100.0)	
Medium adherence	1 (16.7)	2(83.3)	6 (100.0)	>0.999*
Total	17 (14.4)	101 (85.6)	118 (100.0)	
Non-intervention				
Low adherence	14 (12.2)	101 (87.8)	115 (100.0)	
Medium adherence	1 (12.5)	7 (87.5)	8 (100.0)	>0.999*
Total	15 (12.2)	108 (87.8)	123 (100.0)	

*Fisher's exact test

It is evident in Figure 1 that, in the intervention group, only 5% of the patients had medium adherence to drugs. The rest had low adherence before counselling, but after counselling, the rate of medium adherence increased significantly to 31.9% ($p<0.001$). At the same time, there was no significant increase in moderate adherence in the non-intervention group ($p=0.804$).

Table 3. Glycemic control by medication adherence after implementing the counseling program.

Drug adherence	Controlled diabetes No. (%)	Uncontrolled diabetes No. (%)	Total No. (%)	P-value
Intervention				
Low adherence	12 (19.0)	51 (81.0)	63 (100.0)	
Medium adherence	10 (26.3)	28 (73.7)	38 (100.0)	0.391*
Total	22 (21.8)	79 (78.2)	101 (100.0)	
Non-intervention				
Low adherence	11 (11.5)	85 (88.5)	96 (100.0)	
Medium adherence	3 (27.3)	8 (72.7)	11 (100.0)	0.156*
Total	14 (13.1)	93 (86.9)	107 (100.0)	

*Fisher's exact test

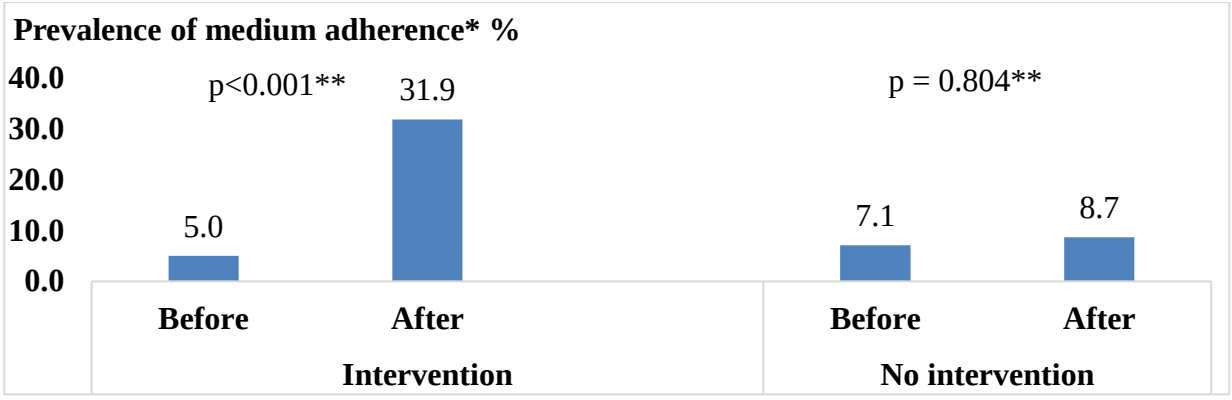

Figure 1. Medium drug adherence before and after the intervention in the study groups.
*Patients had medium adherence, and none had high adherence, **McNemar test

Figure 2 shows a significant improvement in the rate of diabetes control in the intervention group from 13.9% before the intervention to 21.8% after the intervention (p=0.039). However, no significant increase in the rate of diabetes control in the non-intervention group (p=0.804) was found.

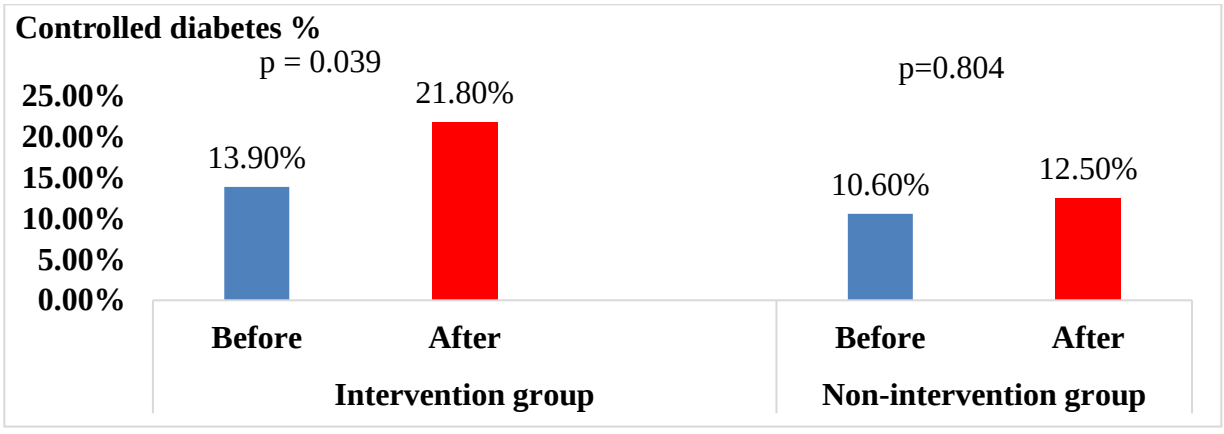

Figure 2. Rate of diabetic control before and after the intervention program in the study group.

Table 4 compares mean glycemic control indicators at baseline and after a control counselling program. It shows no significant differences between the two study groups in the means of blood investigations before or

after counselling. Most trends were exacerbated after 3 months of intervention as FBG increased from 198.0 to 166.8.66 mg/dL ($p<0.001$) and HbA1c increased from 9.2% at baseline to 8.5% ($p<0.001$).

Discussion

We revealed that most patients who visited the Diabetic and Endocrine Center had poor ADMs. Regarding the sociodemographic data, our results demonstrated that the highest percentages of participants were female, housewives, married, and illiterate from an urban area, as supported by another study conducted in the Diabetes and Endocrine Center, Sulaimaniyah city (11).

The current study found that the rate of ADMs was moderate to low, with a significant improvement following the counseling program from 5.0% to 31.9%. These outcomes indicate that diabetic patients give inadequate consideration to their health, which might be due to limitations in the diabetes care program or healthcare services with poor patient counseling on the significance of ADMs. We also indicated that the patients forgot to receive their medicines properly on time when they were not home or had a busy work schedule, making it challenging to adhere to medication plans. Also, some participants stopped taking their medication because they thought their diabetes was correctly controlled or because of their carelessness, lack of financial support, or burdensome work schedules.

While supporting other articles that showed patients' poor or inadequate adherence to treatment, we identified many reasons people could not adhere to treatment and experienced complications. These factors included anti-diabetes drugs' high cost and availability (12). In addition, some patients could not join the program due to a lack of education and skills *(*13).

The current study has shown that glycemic control in the intervention group improved significantly from 13.9% to 21.8% ($p=0.039$), which agrees with a descriptive cross-sectional study conducted at three public hospitals in Johor, Malaysia. ADMs were measured using 8 points of Morisky and found that only 21.8% of T2DM patients had glycemic control (14).

Similar to this study, a quasi-experimental method was implemented at the Internal Medicine Outpatient Polyclinic of West Nusa Tengala Hospital in Indonesia to measure HbA1c before and after treatment as a successful parameter for treating patients with T2DM. Based on the study results, it was shown that there was no significant difference between the data before and after the study in the control group ($p>0.05$) (15).

Furthermore, our study showed no significant association between medication adherence and glycemic control. In addition, a retrospective cohort study of 2463 patients by the National Healthcare Group in Singapore found similar findings. Another group also found no association between ADM and glycemic control (16). Also, the present study's findings agreed with a study that found a no-significant correlation between medication adherence and the HbA1c (17,18). However, these results contrast to the data from a cross-sectional study conducted on 290 diabetic patients at Kenya National Hospital, Kenya, to assess the patient's pharmacological compliance and found a significant association between ADMs and glycemic control (19).

Moreover, our study explored that most of the diabetic patients had an abnormal hyperglycemic test value (HbA1c>9% and FBS>188), which was consistent with a study conducted in Basrah, Iraq, that found HbA1c>7% as a hyperglycemia test exceeded 90% (20). In contrast, most diabetic patients were found to have suboptimal glycemic control in another study in the same area (Basrah, Iraq) (21).

Regarding the effectiveness of patient counselling, the results showed a significant improvement of (rate of adherence and glycemic control) of the intervention group that was supported by the fact that the counselling program results previously showed significant improvements in the outcomes of patients with hypertension and T2DM (22).

Conclusions

Patients' education and medication counselling significantly improved ADMs and glycemic control in people with T2DM.Counselling programs and researcher motivations may improve ADMs and HbA1c management, but there was no significant association between drug use and HbA1c after counselling patients.

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