# Rate and Predictors of Adherence to Treatment among Iraqi Patients with Type 2 Diabetes Mellitus in Al-Najaf City

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## ABSTRACT

*Background:*
*Adherence to treatment is considered a crucial factor in control and management of type 2 diabetes mellitus. Poor controlled diabetes mellitus (DM) leads to progressive complications and high morbidity and mortality rates. Assessment of patients' adherence in our country still needs further studies,*

*Objective:*
*To assess rate and predictors of adherence to treatment among Iraqi patients with type 2 diabetes mellitus in Al-Najaf city.*

*Methodology:*
*We conducted a cross-sectional study during a period of 18 months recruiting 427 patients who were selected from 5 main primary healthcare centers, outpatients clinics of two main hospitals and AlSader diabetes and endocrinology center.*

*Results:*
*Our findings revealed that the overall adherence of our patients was moderate where 63.9% of the patients adhered to their treatment plan, dietary recommendations and doing exercises according to the recommendations of their doctors. The main causes of non-adherence were forgetfulness, ineffective treatment, unavailability of medication, high cost of medication, taking medication only when they have symptoms of hyperglycemia and other reasons.*

*Conclusions:*
*Adherence of patients was in our study was moderate and it was not affected by their socio-demographic characteristics. Longer duration of DM, presence of comorbidities and complications of DM were significantly associated with poor adherence of patients to management plan to control DM.*

*Keywords: Diabetes mellitus, Type two DM, Epidemiology, Management, Adherence, Predictors*

## 1. INTRODUCTION

Diabetes mellitus type 2 (T2DM) is one of the commonest endocrine-metabolic diseases that affect many people worldwide and has a significant burden on their quality of life (1). T2DM, represents a steady growing health problem and considered one of the real challenges to healthcare system in both developing and developed countries. According to the available data, prevalence of T2DM has a significant increase since 1980s, where the number of people with DM raised from 108 million to reach 422 million in 2014, recent estimates show that currently the number of DM patients is almost 536 million worldwide. These numbers proposed to reach up to 800 million by the year 2040. According to these estimates, the prevalence of DM will be almost five-folded in 2040 to reach 10.4% compared to only 2.4% in the year 2000 (2,3). Unfortunately, more than 4 million deaths are directly attributed to DM and more fatalities are indirectly linked to DM through its complication and failure of body organs and systems (4). As the prevalence of DM is folded at each decade, over the past 30 years DM became the 10th most common cause of death. According the World Health Organization Country profiles, 10 countries with different economic statuses rank the first globally with regard to high rates of DM, these countries are China, India, USA, Brazil, Russia, Mexico, Indonesia, Germany, Egypt and Japan (5). From other point of view, majority of DM patients with aged between 40 – 59 years old. However, there is a wide variation in the incidence and prevalence of DMII according to the geographical region. More than 80% of people suffering DM are living in developing countries of low to middle income that add a significant burden and challenges to effective treatment (4).

In Iraq, about 1.4 million of Iraqi people had DM in 2020 and the prevalence rate among Iraqi population varied according to Iraqi provinces from 8.5% to 13.9%. However, an age-adjusted rate of 19.7% was reported in Basrah in 2014 among people aged older than 19 years (6,7).

While genetic predisposition plays a role in determining an individual's vulnerability to type 2 diabetes mellitus (T2DM), the current global epidemic is largely driven by an unhealthy diet and a sedentary lifestyle (8). The majority of people diagnosed with type 2 diabetes mellitus experience at least one complication. The occurrence of complications, which are the primary factors leading to morbidities and death in these people, is influenced by genetic predisposition and being overweight. Furthermore, T2DM is a significant contributor to vision loss, kidney dysfunction,

heart and brain illnesses, nerve damage, and non-traumatic limb amputation. These complications impose a substantial burden on the daily lives of patients (4,9,10). Moreover, it signifies substantial direct and indirect economic costs (11).

Iraq is not exempt from this situation, the epidemiological trend is intricately connected to the increase of chronic degenerative diseases in developing nations, as part of the phenomena of epidemiological transition. The rapid economic and demographic growth observed in Iraq in recent years may be a significant factor contributing to the high prevalence of type 2 diabetes in our nation. This can be attributed to changes in dietary patterns and the aging population, the process of redistributing economic income and adopting more Westernized daily routines (12,13).

Patients' self-care is crucial for the successful management of diabetes (14). Compliance is an essential component of health care that has an impact on every aspect. Inadequate compliance with treatment protocols is a multifaceted issue, particularly for individuals with chronic ailments, and it is significantly eroding the benefits of medical therapy (15). Compliance can be defined as the extent to which a patient's behavior followed medical instructions and advices or respond to recommendations of healthcare provider regarding administration of medications and adhere to the prescribed regimen [8]. Another factor such in addition to the adhering to drug regimens, is following prescribed dietary guidelines, and applying lifestyle modifications (16).Treatment failure is predominantly attributed to noncompliance. Furthermore, failure to comply with medical recommendations results in a lack of metabolic control, which in turn adds to the onset and progression of problems associated with diabetes (17). Patient compliance rates are generally lower for individuals with chronic illnesses compared to those with acute illnesses (18). Diminished compliance not only leads to unfavorable health consequences, but also exerts a substantial influence on healthcare expenses (15). The measurement of compliance involves the utilization of several methodologies, with self-reports and patient interviews being widely recognized as the most prevalent methods (19,20). Various research conducted across different regions of the globe have endeavored to quantify the adherence of individuals with diabetes to their treatment regimens (21–25). Nevertheless, there is a scarcity of data from Iraq. Hence, we administered a survey-based interview to individuals suffering from diabetes in order to assess

their level of compliance with the lifestyle and management guidance provided by their healthcare professionals.

## 2. METHODOLOGY

**Study design and setting:**

This was a cross-sectional study conducted in Al-Najaf City, Middle of Iraq during a period of 18 months, from April 2022 to October 2023. The study included Iraqi patients with type 2 DM who were selected from 5 primary healthcare centers, two main hospitals and Al-Sader center of endocrinology and Diabetes.

**Inclusion criteria:**

1. Iraqi patients with type two DM who attended the specified centers on the day of the interview and agreed to participate in the study

2. Patient aged 20 years or older

3. Both gender were included

**Exclusion criteria:**

1. Newly diagnosed patients

2. Patient who did not complete the interview or did not respond to more than 20% of the questionnaire items

3. Did not have necessary investigations during the last two weeks.

4. The study excluded patients who had severe illness, non-ambulatory, had communication difficulties, had psychiatric disorder, or were above 80 years old (it could introduce recall bias).

**Study sample calculation**

The required study sample was calculated using the standard equation for cross-sectional studies (26) and it was applied with the aid of Open Epi online software (27) according to the following:

$$N = \frac{Z^2 \times P \times (1 - P)}{d^2}$$

*Where*: N: the required study sample, Z: the Z score statistics corresponding to confidence level of 95%. It is equal to 1.96, P. the expected prevalence or proportion of the characteristic in the population (non-adherence), it can obtained from previous similar studies however, because no

previous study was available with accurate adherence rate in our province, we proposed a non-adherence rate of 50%, to get the larger sample size.

d: the precision (margin of error) correspond to confidence level, = 0.05

we applied this equation according to the following assumption

Power = 80%, prevalence of non-adherence : 50%, precision (d) = 0.05, confidence level = 95%.

We got a sample size of 384, we added an extra 10% (38 patient) of the calculated sample and we got a total sample size of 422 and approximated to 450. However, 23 patients were excluded from the study (15 because they refused to participate, and 8 did not complete the questionnaire). The final sample was 427, giving a response rate of 94.9%,

**Sampling technique:**

Each alternate patient who met the eligibility criteria was recruited. Each patient was provided with a detailed explanation of the study process and informed consent was obtained prior to their involvement in the study.

**Study tools and instruments:**

We used a pre-prepared data collection form consisted of three parts; the first for the patient's demographic variables including age, gender, marital status, residence, education, occupation, monthly income, crowding index, family history of DM, patient's weight and height and body mass index. The second part of the questionnaire included the Medical history, clinical data and diabetes related variable, duration of DM, type of treatment, number of medications, physical activity, dietary behavior, presence of any complication and comorbidities, laboratory investigations particularly the glycated hemoglobin (HbA1c), blood sugar, and others.

We used the 8-item Morisky Medication Adherence Scale (MMAS-8) which is adopted from an Indian study conducted by Sahoo et al. and published in Cureus journal in 2022 (28).

The scale consisted of seven questions with binary response options (yes/no), while the eighth question utilized a five-point Likert scale. The study participants were asked to answer each of the 8 items in the MMAS-8.

The measurement of patient adherence to prescriptions was conducted using the recall method, which involved recording the frequency of missed doses during a period of 15 days prior to the interview date. Patients who reported missing more than two doses of treatment over the last 15 days was considered non-adhere (29).

**Statistical analysis:**

We used the statistical package for social sciences (SPSS) version 27 for windows in all analysis and interpretation of our data and findings. The qualitative (nominal or ordinal) variables presented as frequencies and percentage. Numerical (quantitative) variables presented as mean, standard deviation (SD) and ranges accordingly. Qualitative variables were tested with chi-square test. As an alternative, Fisher's exact test was employed when chi-square was inapplicable. Numerical variables were compared using Student's t test. Pearson's and Spearman's correlation tests used to assess the bivariate correlations . P. value ≤ 0.05 considered significant.

## 3. RESULTS

A total of 427 type 2 diabetic patients were enrolled in this study, their baseline socio-demographic characteristics are summarized in (**Table 1**). The duration of DM ranged between 1 – 30 years. However, majority of the patients had a duration of less than 15 years. Almost half of the patients, (49.9%), were on oral hypoglycemic agents (OHA), 15.2% on insulin, 32.8% on combined insulin and OHA while only 2.1% of the patients claimed that they controlled their DM by diet only, (**Table 2**). Different complications have been reported among the studied group, these complications are summarized in (**Table 3**).Distribution of the studied group according to their adherence regarding glycemic control management plan recommendations revealed that 33.7% of the patients did not take their medications regularly, 41.7% did not follow the recommended dietary regimen and 61.4% did not do exercise as recommended  by their physicians, (**Table 4 and Figure1**). Thus the overall non-adherence rate was 36.1% where 154 patients were not adhere to the recommended management plan and 273 patients generally adhere to the recommended management plan (**Figure 2**). The reasons for non-adherence were as followed;  33.7% forgetfulness taking medication, 18.3% thought that treatment is ineffective, 15% unavailable medication, 11.9% high cost of medication, 9.1%  take medication only when they have symptoms of hyperglycemia and 5.2% due to other reasons (**Table 5**).

We found no significant association between socio-demographic characteristics and non-adherence, in all comparisons, P. value > 0.05), (**Figure 3 & Table 6**).

Bivariate Pearson's and Spearman's correlation tests showed that duration of DM was inversely associated with adherence to treatment, i.e. patients with shorter duration were more adhere to treatment than those with longer duration, (R = - 0.458, P. value <0.05, significant). Also patients who had comorbidities were less adhere to treatment (R=-443, P<0.05, significant). Other significant factor associated with non-adherence was presence of complications (R=-632, P<0.05, significant). Neither type of treatment nor physical activity showed significant correlation with adherence status, (P. value >0.05, not significant),   (**Table 7**).

**Table 1. Baseline socio-demographic characteristics of the studied group (N=427)**

| Variable | | No. | % |
|---|---|---|---|
| Age | ≤ 30 | 29 | 6.8 |
| | 31 - 40 | 62 | 14.5 |
| | 41 - 50 | 127 | 29.7 |
| | 51 - 60 | 158 | 37.0 |
| | 61 - 70 | 51 | 11.9 |
| | Mean (SD) | 54.7 (11.2) | - |
| Gender | Male | 198 | 46.4 |
| | Female | 229 | 53.6 |
| Marital Status | Married | 351 | 82.2 |
| | Single | 41 | 9.6 |
| | Divorced/widowed | 35 | 8.2 |
| Residence | Urban | 295 | 69.1 |
| | Rural | 132 | 30.9 |
| Education | Less than primary | 79 | 18.5 |
| | Primary | 134 | 31.4 |
| | Secondary | 151 | 35.4 |
| | University* | 63 | 14.8 |
| Occupation | Employed | 138 | 32.3 |
| | Unemployed* | 289 | 67.7 |
| Family income | Sufficient | 55 | 12.9 |
| | Partially Sufficient | 141 | 33.0 |
| | Insufficient | 231 | 54.1 |
| *University level of education included institution, college and postgraduate levels | | | |

**Table 2. Distribution of duration and treatment received by 427 type 2 diabetic patients in Najaf**

| Variable | | No. | % |
|---|---|---|---|
| Duration of   DM | <5 years | 148 | 34.7 |
| | 5–9 years | 120 | 28.1 |
| | 10–14 years | 98 | 23.0 |
| | ≥15 years | 61 | 14.3 |
| Treatment of DM | OHA | 213 | 49.9 |
| | Insulin | 65 | 15.2 |
| | Combined (Insulin & OHA) | 140 | 32.8 |
| | Dietary controlled | 9 | 2.1 |

**Table 3. Distribution of complications reported among 427 diabetic patients in Najaf, 2022-2023**

| Complication* | No. of patients | % |
|---|---|---|
| Dyslipidemia | 152 | 35.6 |
| Hypertension | 122 | 28.6 |
| Heart disease | 63 | 14.8 |
| Nephropathy | 9 | 2.1 |
| Retinopathy | 5 | 1.2 |
| Diabetic foot | 2 | 0.5 |
| No complication | 262 | 61.4 |
| *Some patients had combined more than one complication | | |

**Table 4. Distribution of the studied group according to their adherence regarding glycemic control management plan recommendations**

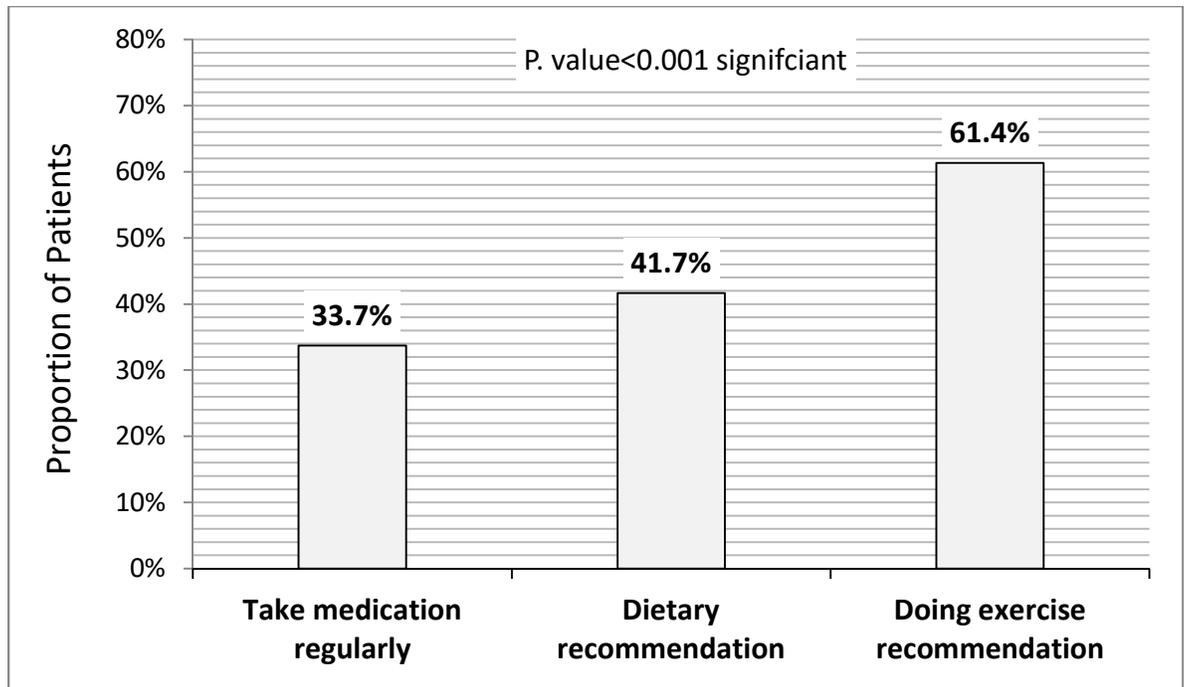| Category | Adhere | | Not Adhere | |
|---|---|---|---|---|
| | No. | % | No. | % |
| Take medications regularly | 283 | 66.3 | 144 | 33.7 |
| Follow dietary recommendation | 249 | 58.3 | 178 | 41.7 |
| Follow doing exercise  recommendation | 165 | 38.6 | 262 | 61.4 |

**Figure 1. Non-Adherence rate for different recommendations in the management plan for glycemic control (N=427)**
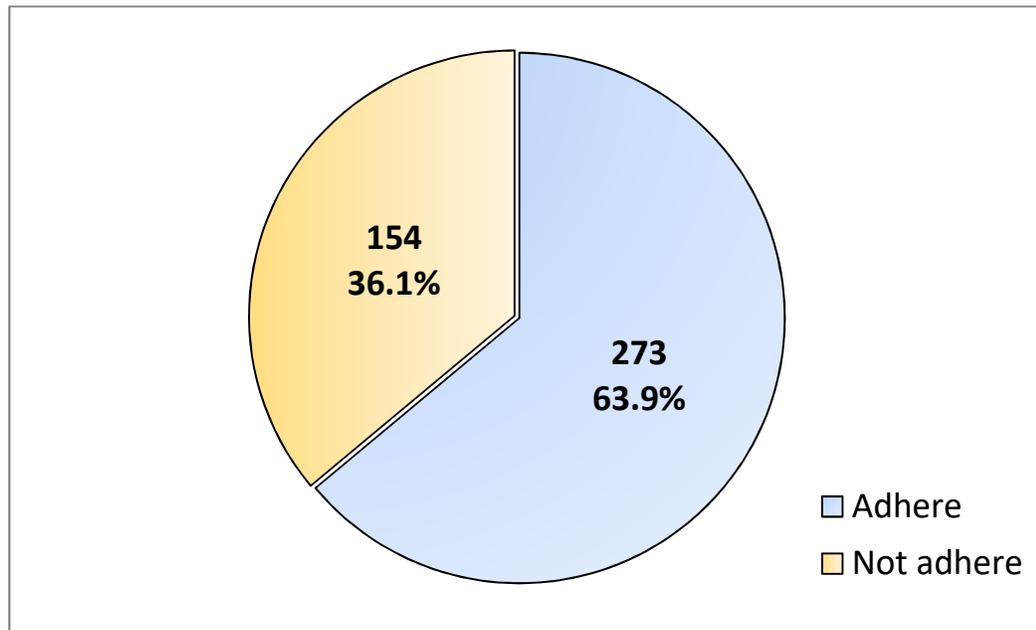


**Figure 2. Overall adherence rate (taking treatment on time and dietary instructions) of the diabetic patients (N=427)**

Table 5. Factors associated with non-adherence to treatment of diabetic patients (N=427)

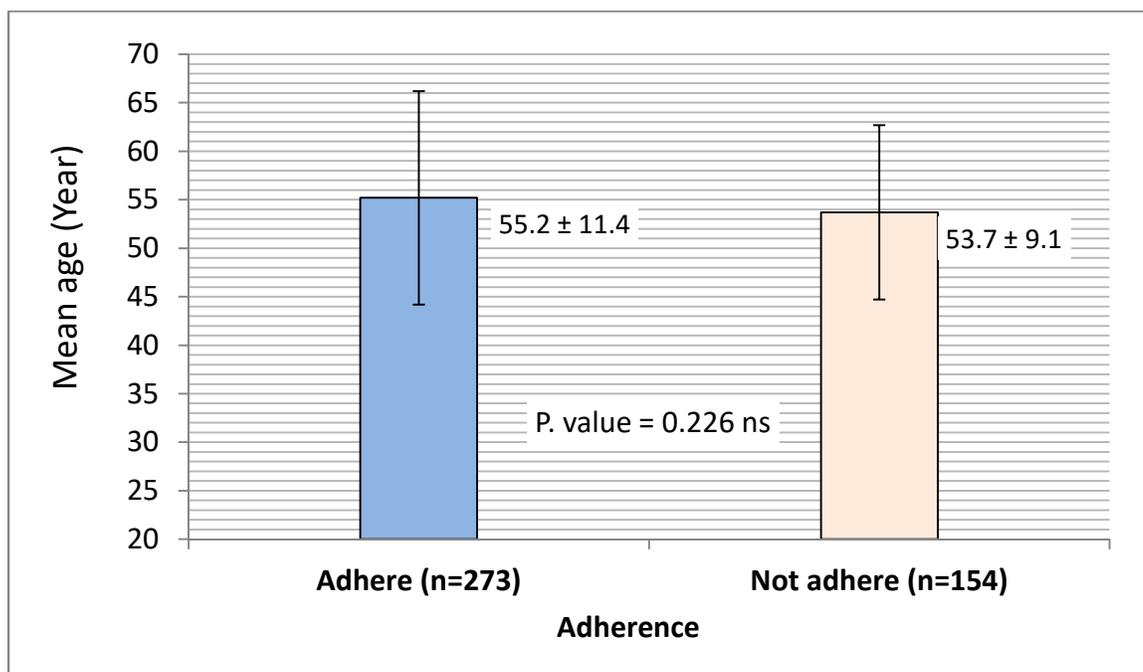| Reasons of non-adherence * | No. | % |
|---|---|---|
| Forget to take medication | 144 | 33.7 |
| Ineffective treatment | 78 | 18.3 |
| Unavailable medication | 64 | 15.0 |
| High cost of medication | 51 | 11.9 |
| Take medication only when have symptoms of hyperglycemia | 39 | 9.1 |
| Other reasons | 22 | 5.2 |
| *some patients reported more than one factor as a reason for non-adherence | | |



**Figure 3. Comparison of mean age of diabetic patients according to their overall adherence to management plan**

Table 6. Cross-tabulation for the association between adherence to management plan recommendations and socio-demographic characteristics of the studied group

| Variable | | Adhere (n=273) | | Not adhere (n=154) | | Total | P. value |
|---|---|---|---|---|---|---|---|
| | | No. | % | No. | % | | |
| Gender | Male | 129 | 65.2 | 69 | 34.8 | 198 | 0.691 ns |
| | Female | 144 | 62.9 | 85 | 37.1 | 229 | |
| Marital Status | Married | 221 | 63.0 | 130 | 37.0 | 351 | 0.443 ns |
| | Single/Divorced /widowed | 52 | 68.4 | 24 | 31.6 | 76 | |
| Residence | Urban | 194 | 65.8 | 101 | 34.2 | 295 | 0.285 ns |
| | Rural | 79 | 59.8 | 53 | 40.2 | 132 | |
| Education | Illiterate | 50 | 63.3 | 29 | 36.7 | 79 | 0.881 ns |
| | Primary | 82 | 61.2 | 52 | 38.8 | 134 | |
| | Secondary | 98 | 64.9 | 53 | 35.1 | 151 | |
| | University | 41 | 65.1 | 22 | 34.9 | 63 | |
| Occupation | Employed | 87 | 63.0 | 51 | 37.0 | 138 | 0.875 ns |
| | Unemployed | 186 | 64.4 | 103 | 35.6 | 289 | |
| Family income | Sufficient | 34 | 61.8 | 21 | 38.2 | 55 | 0.814 ns |
| | Partially Sufficient | 93 | 66.0 | 48 | 34.0 | 141 | |
| | Insufficient | 146 | 63.2 | 85 | 36.8 | 231 | |

Table 7. Results of bivariate correlation analysis between adherence score and other variables

| Variable | R | P. value |
|---|---|---|
| Duration of DM | -0.458 | 0.006 sig |
| Comorbidities | -0.443 | 0.017 sig |
| Complications | -0.632 | 0.002 sig |
| Type of treatment | 0.093 | 0.705 ns |
| Physical activity | 0.066 | 0.814 ns |
| R: correlation coefficient, sig: significant, ns: not significant | | |

## 4. DISCUSSION

Adherence to treatment is considered a crucial factor in control and management of type 2 diabetes mellitus and is defined as the degree to which a person's behaviors - taking medication, dietary monitoring and performing physical activity - are adjusted to medical indications. The impact of lack of therapeutic adherence in diabetic patients has been previously studied using various methodologies. In a registry published in 2012, it was revealed that only 56% of patients with T2DM achieved metabolic control, despite the fact that approximately 78% of patients were receiving treatment with oral antidiabetics or insulin (30) . On the other hand, according to other studies, the non-adherence rate was between 54.4% and 58.9%  among patients with T2DM who take oral antidiabetics and close to 25% in patients on insulin (24,31,32).

To our knowledge, this is to date the first study carried out in our province that attempts to explore the current situation of therapeutic adherence in patients with T2DM .

As other authors consider in the case of other chronic diseases, therapeutic non-compliance constitutes a major health problem that directly affects patients, regardless of their age and clinical situation. Firstly, it reduces the possibility of achieving adequate metabolic control, increasing morbidity and mortality, which has already been demonstrated in other studies: an increase in adherence to oral antidiabetics of 10% means a decrease in HbA1c of 0.1% (33). Poor control is associated with an increase in hospitalizations due to complications and reduces the patient's quality of life (34), both facts being known by the experts consulted in the present study. In the context of T2DM, lack of adherence is, along with lack of treatment intensification or therapeutic inertia, is a primary factor contributing to inadequate metabolic control and is linked to increased cardiovascular morbidity and death. In fact, adherence and therapeutic inertia seem to be associated, and patients with a higher compliance rate are more likely to have their treatment intensified in the following 12months after not achieving adequate metabolic control (HbA1c<7%) when compared to patients with low adherence rates  (35,36). In the majority of patients with T2DM, pharmacological treatment and recommendations based on lifestyle modification are prescribed, followed and controlled in the primary care setting . Therefore, doctors and nursing staff at this level of care are the main health professionals involved in acting on those patients in whom the predetermined therapeutic objectives are not achieved. It is necessary to have the necessary training and tools to identify this phenomenon,

and not attribute the cause of poor metabolic control to an insufficient therapeutic response that would lead to unnecessary tests, changes in prescription or intensification of treatments that could increase the risks for the patient. In relation to the detection and measurement of adherence, the clinical judgment of the doctor or the information given by the patient does not seem to be sufficient in the case of T2DM. As this is a widespread problem in the assessment of adherence, different standardized measurement methodologies have been validated, being able to differentiate between direct measurements (blood concentration or direct observation of intake) or indirect measurements (patient questionnaires, evaluation of response to treatment, etc.) (37). According to the results of our study, it seems that indirect measurement methods, such as the Morisky-Green 8-item tests, is the most used in the case of patients with T2DM. Regarding the question of whether it would be necessary to develop a test specifically designed to measure the degree of therapeutic adherence in T2DM, it is not possible to reach a consensus in terms of agreement or disagreement (37). Our finding regarding the non-adherence rate we reported that 33.7%  of the patients did not take their medications regularly, 41.7% did not follow the recommended dietary regimen and 61.4% did not do exercise as recommended  by their physicians, with an overall non-adherence rate was 36.1%. We reported the main reasons for non-adherence as mentioned by the patients as followed: 33.7% due to forgetfulness, 18.3% ineffective treatment, 15% unavailable medication, 11.9% high cost of medication, 9.1% take medication only when they have symptoms of hyperglycemia and 5.2% due to other reasons. Our findings were in line with that reported in previous Iraqi study in Duhok, where Allela et al. (38) used MMAS-8 and found that 72% of participants had low adherence rate which is close to our findings. Close to our rates of adherence, in another Iraqi study conducted in Basrah, Aladhab and Alabbood (39) documented that 65.4% of patients were adhere and taking their medications regularly at the right time. They also reported that forgetfulness was the commonest cause of non-adherence which was reported by 48.8% in that study. Additionally, Aladhab and Alabbood found that almost 41% of participants did not practice exercises and almost 67%  did not followed the diet recommendation. Our rates of adherence were lower than that reported in other Iraqi study in Erbil where Saleh A.M. (40) found that almost 85.4% of diabetic patients taking their medications regularly, 78.8% followed the recommended diet and 56.4% doing exercises as recommended by their doctors. However, the difference in the rates of

adherence could be attributed to the nature of included patients where Saleh A.M. (40) included diabetic patients of both types of DM; type I and II, and included children also who were at one year and older and the age ranged between 1-80 years. Children may be a confounder to increase the adherence rates because they were strictly monitored by their parents and care giver. In India, lower adherence rate was reported among Indian T2DM patients compared to our study and the previous Iraqi studies where Sahoo et al. (37) who also used MMAS-8 questionnaire, concluded that medication adherence was only 34.14% .

In Cameroon, Aminde et al. (24) found that 54.4% of the patients were not adhere to medication and the main reason of non-adherence was forgetfulness, cost and disappearance of symptoms. In our study we did not found any significant correlation between adherence level and sociodemographic characteristics of the studied group which is agreed that reported in previous Iraqi studies (7,38–40).

We found that comorbidities and presence of complications negatively affected the adherence of patients and this could be explained that presence of these factors may increases the number of medications that have to be used by the patients which may interfere with their adherence to antidiabetic medications in addition to the long term use of medication lead to decrease in the adherence. However, reasons of non-adherence are multifactorial and it is not easy to be well addressed (33,41,42). However, the causes that motivate a chronic patient not to comply with the given prescriptions have been widely described previously. Classically, the multidimensional model described by the WHO (41)has been adopted, which identifies 5 groups of causal factors: variables related to the patient, the treatment, the disease, the health system, and socioeconomic variables. Specifically, the panel of experts highlights that in the case of patients with T2DM, a complex treatment regimen - which may include lipid-lowering and antihypertensive agents -, the longer duration of the disease, poor healthcare professional-patient communication, lack of a Adequate social support, having negative beliefs about the disease and treatment, depression or a low level of health literacy are main causes of non-compliance. There are different studies on diabetics that coincide with the present study when it comes to establishing the different causes of non-compliance (43–46).

## 5. CONCLUSIONS

The overall adherence of our patients was moderate compared to some other countries, however, our findings were comparable to that reported in previous National studies. The main causes of non-adherence were forgetfulness, ineffective treatment, unavailability of medication, high cost of medication, take medication only when they have symptoms of hyperglycemia and due to other reasons. Adherence of patients was not affected by their socio-demographic characteristics. Longer duration of DM, presence of comorbidities and complications of DM were negatively affected the adherence of patients to management plan. We recommend to perform further studies for more precise assessment.

**Ethical Approval:**

All ethical issues were approved by the author. Data collection and patients enrollment were in accordance with Declaration of Helsinki of World Medical Association , 2013 for the ethical principles of researches involving human subjects. Verbal informed consent was obtained from all participants.

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