

Adherence and satisfaction with oral hypoglycemic medications: a pilot study in Palestine

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Abstract *Objectives* Diabetes mellitus is a chronic progressive disease characterized by numerous health complications. Medication adherence is an important determinant of therapeutic outcome. Few studies on medication adherence have been published from the Arab countries. Therefore, the objective of this pilot study was to assess hypoglycemic medication adherence and its association with treatment satisfaction. *Setting* Military Medical Services clinic in Nablus, Palestine. *Methods* This is a cross sectional descriptive study. A convenience sample of 131 diabetic patients was studied. The 8-item Morisky Medication Adherence Scale (MMAS-8) and Treatment Satisfaction Questionnaire for Medication were used to assess adherence and treatment satisfaction, respectively. Statistical Package for Social Sciences was used for statistical analysis. *Main outcome measure* Level of adherence, treatment satisfaction and association between adherence and treatment satisfaction among diabetic patients. *Results* According to MMAS-8, 50 patients

(38.5%) had a high adherence, 58 (44.6%) had a medium adherence and 22 (16.9%) had a low adherence rate. The mean scores of satisfaction domains were 71 ± 17.6 and 95 ± 16.4 for effectiveness (EFF) and side effects (SE), respectively. Adherence score was a positively and significantly correlated with EFF satisfaction domain ($P < 0.01$) and age ($P = 0.01$). Similar significant correlation was found between adherence level and duration of illness ($P = 0.047$). However, adherence was not significantly associated with gender ($P = 0.2$), number of hypoglycemic medications ($P = 0.5$) or SE satisfaction domain ($P = 0.2$). *Discussion and conclusion* The majority of diabetic patients in this pilot study were non-adherent. Improving patients' treatment satisfaction will improve treatment adherence.

Keywords Adherence · Diabetes mellitus · Palestine · Satisfaction

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Impact of findings on practice

- Adherence can be assessed using simple self-reported methods.
- Effective hypoglycemic therapy might increase patients' treatment satisfaction, medication adherence and clinical outcome.
- Translated international scales might be a useful tool to improve clinical pharmacy research and practice in Palestine.

Introduction

Diabetes mellitus (DM) is a global health disease. It can lead to serious acute and chronic complications if poorly

treated. It was estimated that approximately 171 million people in the world had DM in the year 2000 and the total number is projected to rise to 366 million in 2030 [1]. It is striking that Arab world (North Africa, Middle East, and Gulf area) will have the highest increase in percentage of people with DM in 2030 compared to other parts of the world [1]. This increase in prevalence of DM in the Arab world necessitates implementing preventive health policies as well as implementing therapeutic measures to decrease cost and complications in patients with DM. Adherence to oral hypoglycemic medications is a key factor in achieving therapeutic success and studies have shown that non-adherence results in serious clinical and economic consequences [2–4]. Few studies have been published in the Arab world in general and in Palestine in particular about the extent of adherence to oral hypoglycemic agents in patients with DM [5–8]. Furthermore, a recent study have shown that racial differences in adherence to oral hypoglycemic drug therapy persist even with equal access to medication and that early and continued emphasis on adherence from initiation of therapy may reduce persistent racial differences in medication use and clinical outcomes [9]. Treatment satisfaction among diabetic patients is an important determinant of patient's overall health-related decisions like adherence [10]. Treatment satisfaction has been shown to be associated with better glycemic control and lesser morbidity [10, 11].

Medication adherence could be measured by direct or indirect methods. Examples of direct methods include measuring the level of medication or its metabolite in blood or urine while examples of indirect methods include self-reports, pill count, prescription refills, and electronic monitors [12]. Self-reporting is considered the simplest and the least expensive method. George et al. [13] had found that when a valid scale like Morisky questionnaire [14, 15], is used to assess medication adherence, self-report scores are accurate with both sensitivity and specificity of over 70%.

Aim of the study

The aims of this study were to assess medication adherence and its association with treatment satisfaction among type 2 diabetic patients. This study is one of the few about medication adherence and treatment satisfaction among type 2 diabetic patients in the Arab world. Furthermore, contrary to previous studies an adherence measuring scale that have been tested and validated by other languages in other non-Arab countries will be used in this study [5–8].

Method

Study design and patient selection

This pilot cross sectional descriptive study was conducted between October 2010 and January 2011 at the Military Medical Services clinic in Nablus, Palestine which provides medical services for military personnel and their families who suffer from chronic diseases. Approval to perform the study was obtained from the Military Medical Services authorities. In addition, verbal consent was given by each patient before the start of the study. Inclusion criteria for the study were: (1) a diagnosis of type 2 DM, documented in the medical files; (2) taking at least one oral hypoglycemic agent and 3) medications had not been changed in the last 6 months. The sample size was calculated based on previously reported non adherence rates of approximately 60%, z value of 1.96 for 95% CI and a total width of CI of 20%. The estimated sample size would be at least 92 patients. A convenience sample of 131 patients met the inclusion criteria and 130 agreed to participate and were asked to complete two scales to assess medication adherence and treatment satisfaction scale. After patients gave verbal consent, they were asked to complete the scales in the clinic. The two scales were administered together and took <20 min to complete.

Assessment and measures

The instrument used in this study consisted of three parts: part one collected socio-demographic, clinical and medication data obtained directly from patients to their medical files; part two was medication adherence test, and the last part was the treatment satisfaction test. Medication adherence was tested using Arabic version of the validated eight-item Morisky Medication Adherence Scale (MMAS-8) [14, 15]. English version of the MMAS-8 was translated into Arabic and was approved by professor Morisky through e-mail communication. The translation process was carried out according to the following procedure: (1) A forward translation of the original questionnaire was carried out from English to Arabic language by two qualified independent, native linguistic expert translators (2) A back translation from Arabic language to English was carried out by two different translators. (3) The back translated questionnaire was tested and approved by the developer through e-mail. The Arabic version of MMAS-8 is an 8-item questionnaire with 7 yes/no questions while the last question was a 5-point Likert scale. Based on the scoring system of MMAS, adherence was rated as follows: high adherence ($=8$), medium adherence (6 to <8) and low adherence (<6). Patients who had a low or a moderate rate of adherence were considered as non-adherent.

Treatment satisfaction was tested using the Arabic version of Treatment Satisfaction Questionnaire for Medication (TSQM 1.4) which the researchers obtained from Quintiles Strategic Research Services. The TSQM 1.4 is a 14-item psychometrically robust and validated instrument consisting of four scales [16]. The four scales of the TSQM 1.4 include the effectiveness (EFF) scale (questions 1–3), the side effects (SE) scale (questions 4–8), the convenience (CONV) scale (questions 9–11) and the global satisfaction (GS) scale (questions 12–14). The TSQM 1.4 domain scores were calculated as recommended by the instrument's authors, which is described in detail elsewhere [17, 18]. The TSQM 1.4 domain scores range from 0 to 100 with higher scores representing higher satisfaction on that domain. For the purpose of this study we calculated and analyzed the first two domains: EFF and SE satisfaction domain.

Data analysis

Continuous variables were expressed as mean \pm SD. Kolmogorov–Smirnov test and the Shapiro–Wilk test were used for normality test. Results of both tests suggest normal distribution of tested variables. Difference in means among groups was carried out using one-way ANOVA with the Tukey post-hoc test. Association between categorical variables was carried out by Chi square test. Independent Samples *T* test was used to compares means of continuous variables of two groups. Pearson correlation was used to assess correlations between adherence score and continuous variables while Spearman rank test was used to test correlation when one of the tested variables is ordinal. All statistical analyses were conducted using Statistical Package for Social Sciences (SPSS; version 16.0) for Windows. The conventional 5% significance level was used throughout the study.

Results

A convenience sample of 131 diabetic patients met the inclusion criteria during the study period. One hundred and thirty patients agreed and gave a verbal consent to participate giving a response rate of 99.2%. Eighty-three (63.8%) patients were males and 47 (36.2%) patients were females. Mean age of patients was 56.3 ± 9.8 years (range 33–78) and mean duration of illness was 8.2 ± 5.8 years. Most patients (95, 73.1%) had co-morbid diseases, mainly hypertension. The average number of oral hypoglycemic medications used by patients was 1.8 ± 0.53 medications (range 1–3). The majority of patients (97, 74.6%) were on combination therapy. Most commonly used oral hypoglycemic medication was metformin, followed by glimepiride.

Details regarding demographic characteristics of patients included in the study are shown in Table 1.

According to MMAS-8, fifty (38.5%) patients had a high adherence, 58 (44.6%) had a medium adherence, and 22 (16.9%) had a low adherence rates (Fig. 1). This means that 61.5% of patients were non-adherent. The mean adherence score of 6.8 ± 1.3 suggests that medication adherence among our study sample is within a medium rate. Analysis of responses to MMAS-8 showed that about 37.7% of patients forgot to take their medications; 18.5% of patients missed taking their medication for reason other than forgetting in the past 2 weeks before the interview; 8.5% stopped taking their medication without doctor counseling when they felt worse upon taking them; 6.9% forgot to take their medications with them when leave home for long time; 3.8% didn't take their medication in the day before interview; 14.6% stopped taking their medication when they felt that their health is under control; and 26.6% felt hassled about sticking to their treatment plan. As for remembering to take their medications; 3.1% of the patients faced a difficulty in doing this once in a while; 4.6% of the sample sometimes had difficulties in remembering to take their medications; 2.3% of patients usually found difficulties; while none of diabetic patients faced these difficulties all the times. However, 90% didn't

Table 1 Demographic and clinical characteristics of patients stratified by adherence level

Variables	All patients	High adherence	Medium adherence	Low adherence
Age (years)	56.4 \pm 9.8	58.2 \pm 1.2	56.3 \pm 1.4	52.5 \pm 2
Duration of the disease (years)	8.3 \pm 5.8	9.3 \pm 0.80	8.2 \pm 0.84	6.4 \pm 0.87
Gender				
Male, <i>n</i> (%)	83 (63.8)	27 (32.5)	39 (47)	17 (20.5)
Female, <i>n</i> (%)	47 (36.2)	23 (49)	19 (40.4)	5 (10.6)
Level of education				
Illiterate (%)	26 (20)	12 (46.15)	12 (46.15)	2 (7.7)
Primary education (%)	44 (33.8)	21 (47.7)	17 (38.6)	6 (13.6)
Secondary education (%)	25 (19.2)	7 (28)	11 (44)	7 (28)
Diploma or university degree	35 (27)	10 (28.6)	18 (51.4)	7 (20)
Presence of other chronic diseases				
Yes, <i>n</i> (%)	95 (73.1)	39 (41.1)	45 (47.4)	11 (11.6)
No, <i>n</i> (%)	35 (26.9)	11 (31.4)	13 (37.1)	11 (31.4)
Type of therapy				
Monotherapy, <i>n</i> (%)	33 (25.4)	11 (33.3)	15 (45.5)	7 (21.2)
Combination therapy, <i>n</i> (%)	97 (74.6)	39 (40.2)	43 (44.3)	15 (15.5)

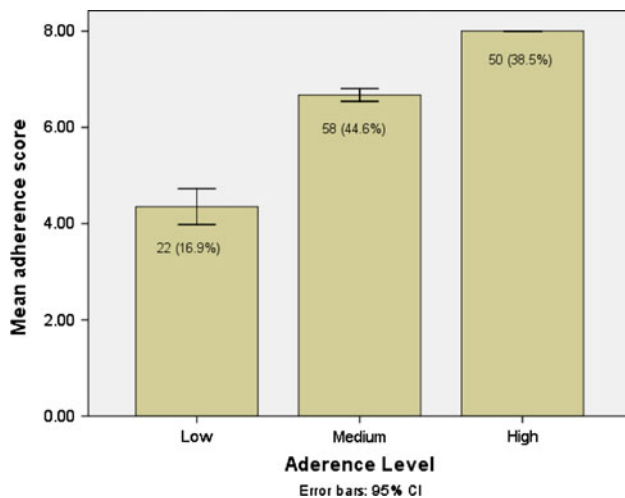


Fig. 1 Distribution of patients based on adherence level. *N* (%) inside the bar represents the frequency and percentage of patients in each category

show any difficulty in remembering to take their medication on time. Response to each question in the MMAS-8 is shown in Table 2.

Analysis of correlations showed that there was a significant and positive correlation between age and adherence score tested as continuous variables ($P = 0.01$, $r = 0.22$; Pearson correlation test). There was also a significant correlation between duration of illness and adherence level tested as a continuous and ordinal variables ($P = 0.047$; Spearman correlation test). There was a significant association between level of adherence and presence of co-morbid disease. People having co-morbid diseases were more adherent ($P = 0.03$; χ^2 test) than

patients with no co-morbid diseases. No significant difference in adherence score was found between male and female patients (mean difference = -0.311 ; 95% CI = $[-0.8$ to $0.17]$; $P > 0.05$; Independent Samples *T* test). Similarly, no significant difference was found between patients on monotherapy or combination therapy (mean difference = -0.35 ; 95% CI = $[-0.9$ to $0.24]$; $P > 0.05$; Independent Samples *T* test).

The means \pm SD of satisfaction domains were 71.03 ± 17.64 and 95.00 ± 16.42 for EFF and SE satisfaction domains. There was a positive and significant correlation between adherence score and EFF score ($P = 0.005$, $r = 0.242$; Pearson correlation test), but not with SE score ($P = 0.191$; Pearson correlation test). Scatter plots of adherence scores versus EFF and SE scores are given in Figs. 2 and 3. Repeated analysis using one way ANOVA yielded similar results regarding the correlation between adherence scores and EFF and SE satisfaction scores. Significant difference was found in EFF scores among the three adherence categories ($P = 0.001$; $F = 8.4$). Patients in the high adherence category had significantly higher EFF satisfaction scores compared to those in low (mean difference = -13.7 ; $P = 0.005$) or medium (mean difference = -11.7 ; $P = 0.001$) adherence categories (Fig. 4). No significant difference was found in SE scores among the three adherence categories ($P > 0.05$; $F = 1.6$).

Discussion

In this pilot study, we aimed to investigate adherence to oral hypoglycemic medications and its association with

Table 2 Response of patients to 8 questions in Morisky scale

Morisky item	Yes, <i>n</i> (%)	No, <i>n</i> (%)
Do you sometimes forget to take your hypoglycemic medicine?	49 (37.7)	81 (62.3)
Sometimes, people do not take their medication for some reasons other than forgetfulness. Have there been any days over the past 2 weeks you did not take your hypoglycemic medicine?	24 (18.5)	106 (81.5)
Have you ever reduced or stopped taking your hypoglycemic medicine without telling your doctor because you felt that your condition has become worse when you had taken the medicine?	11 (8.5)	119 (91.5)
Do you, sometimes, forget to bring your hypoglycemic medicine with you when you travel or leave home?	9 (6.9)	121 (93.1)
Did you take your hypoglycemic medicine yesterday?	125 (96.2)	5 (3.8)
When you feel that your health condition is under control, do you sometimes stop taking the hypoglycemic medicine?	19 (14.6)	111 (85.4)
Taking medication daily may not appeal to some people. Do you feel dissatisfaction or resentment or confusion due to your daily commitment to take your hypoglycemic medicine?	34 (26.2)	96 (73.8)
How often do you face difficulties remembering to take all your medications?		
Never/rarely	117 (90)	
Once in a while	4 (3.1)	
Sometimes	6 (4.6)	
Usually	3 (2.3)	
Always	0 (0)	

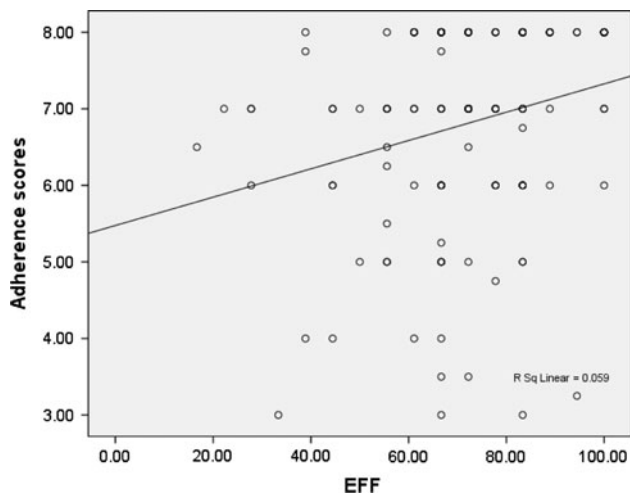


Fig. 2 Scatter plot for the correlation between EFF satisfaction scores with adherence with r^2 value of 0.06. *EFF* effectiveness

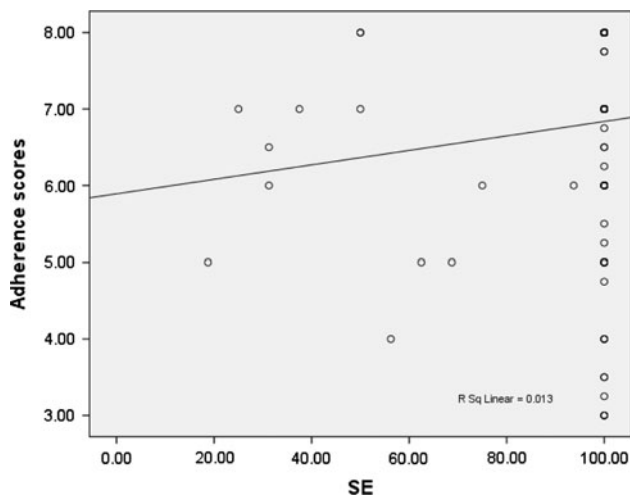


Fig. 3 Scatter plot for the correlation between SE satisfaction scores with adherence with r^2 value of 0.013. *SE* side effects

treatment satisfaction among a sample of Palestinian patients with type 2 DM. In our study, the majority (61.5%) of patients were non-adherent. Adherence was found to be positively correlated with age and duration of illness but not with gender or number of oral hypoglycemic agents. Furthermore, we also found that adherence was positively correlated with patients' satisfaction regarding medication *EFF* but not with *SE* satisfaction domain.

There are few studies that measured adherence among diabetic patients in the Arab world. In a self-reported study in Palestine by Sweileh et al. [6] only one-third of the patients showed good adherence. In Egypt, Shams and Barakat also used self-reported measures to assess adherence and found that about 40% of patients in the study had

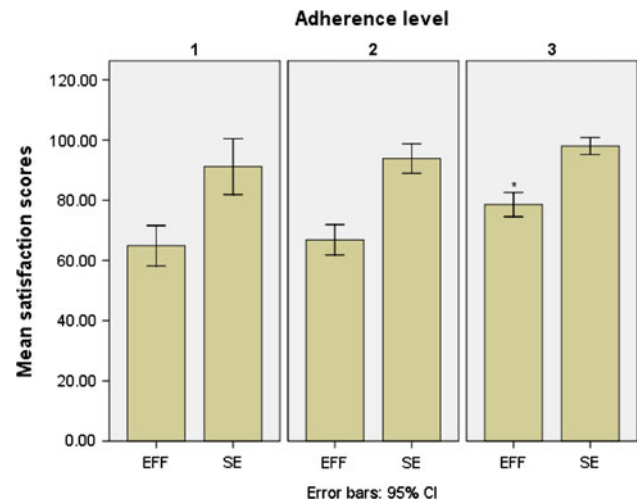


Fig. 4 Means of treatment satisfaction scores based on adherence level. *EFF* effectiveness, *SE* side effects. Adherence levels: 1 = low, 2 = medium, 3 = high. *N* for the three categories was as follows: high = 50, medium = 58, low 22 patients. *Statistically significant compared to corresponding domains in other adherence levels. One way ANOVA test was used to compare between groups after testing for normality of the data. High versus low adherence (mean difference = -13.7 ; $P = 0.005$). High versus medium (mean difference = -11.7 ; $P = 0.001$). Mean scores of *EFF* are: high adherence = 78.6 ± 14.2 , medium adherence = 66.9 ± 19.1 , low adherence = 64.9 ± 14.1

good adherence to oral hypoglycemic medications. In Saudi Arabia, Khattab et al. [5] compared the prescribed medications with the medications in the containers and found that more than 80% had good adherence [7]. A systematic review of adherence to medication for diabetes both in developing and developed countries showed that average adherence to oral hypoglycemic medications ranges from 36 to 93% [19]. It is believed that measuring medication adherence among diabetic patients is a complex process because it involves several factors [7]. Therefore, results of adherence studies remain as estimates of level of adherence to be used as guidelines for health policy makers with regard to DM therapy and control.

Many studies in different countries have generated different or similar findings to those obtained in our study regarding factors associated with hypoglycemic medication adherence. For example, in an Egyptian study, age and treatment satisfaction were significantly associated with adherence [8]. These findings suggest that elderly patients might appreciate the consequence of non-adherence more than younger patients. In a study in USA among patients with DM in a managed care organization, authors of the study found that patients receiving monotherapy with an oral hypoglycemic medication exhibited significantly greater adherence compared with patients on combination therapy [20]. In a study carried out in Southwestern Nigeria, the authors found that gender was significantly associated

with adherence and that males have higher tendencies to forget taking their hypoglycemic medications [21]. In a study carried out in USA, the authors identified three motivating factors to improve medication adherence among diabetic patients. First, patients should know that diabetes medications work effectively to lower blood glucose. Second, patients should know how to manage medications' adverse effects. Thirdly, patients' understanding of medications benefits [22]. A study reported that the presence of diabetic complications, difficulties in adherence to diet, exercise, medication, or attending follow-up appointments were significantly associated with lower treatment satisfaction [23]. Medication adherence and treatment satisfaction would be reflected on the blood level of HbA1C which is an important indicator of glycemic control [11, 23].

In our study, unintentional forgetfulness was the most commonly cited reason reported by respondents for non-adherence (question # 1 in Morisky scale). One-third of respondents reported forgetting their daily oral hypoglycemic medications. Another important factor reported for non-adherence by diabetic patients was dissatisfaction with daily dosing (Question # 7 in Morisky scale). This necessitates the need to increase patients' understanding and knowledge of DM treatment regimens. The more information and understanding that a patient has regarding a disease and pharmacologic therapies, the more they are likely to adhere to their medications [24]. Primary care providers should emphasize the importance of adherence to the time, quantity and mode of administration of hypoglycemic medications. Pharmacists might also help patients in developing cues to remember time of medication by linking drug administration to patients' routine activity. Information should be given to patients about what he should do when he forgot to take his medications. Teaching patients about the significance of HbA1c and the potential diabetic future complications might encourage patients to be serious in taking his medication especially if given information about the potential protective effects of hypoglycemic agents on the long term.

Our results showed that most patients in the study sample had high satisfaction with SE profile of their oral hypoglycemic agents. However, there was a wide range of satisfaction among study patients with regard to EFF of their oral hypoglycemic therapy. Furthermore, differences in satisfaction with regard to EFF were associated with differences in adherence where patients with the highest satisfaction regarding EFF had the highest adherence level. A study carried out on 2,499 diabetic patients using WHO-diabetes Treatment satisfaction questionnaire (DTSQ) has found an inverse relationship between treatment satisfaction and HbA1C [25]. In a study carried out to quantify the prevalence of tolerability issues among patients with type 2 DM and its association with treatment adherence and

satisfaction, the authors concluded that optimizing oral hypoglycemic therapy of type 2 DM by improving tolerability may increase patient satisfaction, medication adherence and health related-quality of life [26]. It has been reported that there are differences between different classes of oral hypoglycemic medications in terms of tolerability and therefore in terms of treatment satisfaction and medication adherence [27]. Differences in tolerability among different drug classes might result in switching medications and reduced adherence [28–30].

Medication adherence has also been linked to psychological factors. For example, perceived seriousness of diabetes, vulnerability to complications, and the efficacy of treatment, can predict better adherence [31]. It is expected that patients adhere well when the treatment regimen seems effective to the patient and when they believe the benefits exceed the costs.

Important points regarding our study include the fact that this is the first study to use international scales to assess adherence and satisfaction in diabetic patients in Palestine. Furthermore, the homogeneity of patients made our conclusions more accurate. All patients have insurance and do not need to purchase medications. Therefore, cost is not a barrier for adherence. Our study has few limitations. First, the sample size may be small and did not allow detection of significance in statistical analysis. Second, data about glycosylated hemoglobin levels which would be an indicative on the level of diabetes control and adherence among patients were lacking. Another limitation is that we used the Arabic version of MMAS-8 which hasn't been validated yet. Finally, the self-reported nature of measurement, the cross sectional design, and the CONV sampling method are considered points of limitation in the study.

Conclusions

Most of patients in this study were non adherent. Low adherence was associated with low satisfaction regarding treatment EFF. The choice of effective treatment regimen will improve satisfaction and therefore improve adherence. It's very important to raise the awareness of diabetic patients about the importance of medication adherence and the consequences of non-adherence. Validation of Arabic MMAS-8 scale through measurement of glycosylated hemoglobin is needed.

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Conflicts of interest None.

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