



Adherence to antidiabetic medication during the month of Ramadan among diabetes mellitus patients in the kingdom of Saudi Arabia

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Article History	Abstract
Received: Revised: Accepted	<p>Background: Ramadan may lead to reduced adherence to antidiabetic medications among Saudi diabetes patients due to fasting, changes in daily routine, social and cultural influences, health risks, and inadequate awareness. This study aimed to assess the Saudi population adherence to the diabetes management medication in Ramadan.</p> <p>Methodology: A convenience sampling method was used to recruit participants for the study. Participants were sourced from social media platforms, diabetes mellitus patient groups, and healthcare providers groups. The Medication Adherence Rating Scale (MARS), a tool, was used to assess medication compliance.</p> <p>Results: A total of 384 individuals were included in this study, 20.3% were from Riyadh, 52.3% were males, 35% aged 31-50 years, and 64.1% had type 2 diabetes mellitus of participants. Age between 31-50 years was negatively associated with compliance ($\beta = -1.06$, $p = 0.002$), while age between 51-65 years is positively associated ($\beta = 1.00$, $p = 0.003$). Being male was negatively associated with compliance ($\beta = -0.72$, $p = 0.001$). Different fasting behaviors like non-fasting one day or more ($\beta = -2.92$, $p < 0.001$) and fasting all month ($\beta = -2.90$, $p < 0.001$), significantly affect compliance scores with negative associations indicating lower compliance during fasting periods. Various HbA1c levels were significant predictors of compliance. Higher HbA1c levels were associated with increased compliance.</p> <p>Conclusions: The study reveals that age, gender, fasting behaviors and HbA1c levels significantly impact medication compliance among patients with diabetes mellitus during Ramadan.</p> <p>Keywords: diabetes mellitus, medication compliance; Saudi Arabia; Ramadan</p>
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1. Introduction

Every year, during the holy month of Ramadan, millions of Muslims fast throughout the world, carrying out a custom that is considered a cornerstone of the ritual requirement of the Islamic faith. Muslims refrain from eating, drinking, and engaging in sexual activity from dawn until nightfall when they break their fast with a meal known as Iftar. They also consume a pre-dawn meal called Suhoor. Fasts can range from 10 to 18 hours or longer depending on the region and season. In addition to fasting, many Muslims continue to work during the day and may adjust their sleeping patterns to participate in additional night prayers known as Taraweeh, which can involve standing for hours in collective prayer [1]. In a 2013 Pew Research survey of 38,000 Muslims worldwide, 93% of the respondents said that they fasted during Ramadan [2]. This includes Muslims with type 1 and type 2 diabetes. Those with type 1 and type 2 diabetes may be more susceptible to negative health effects when fasting. Patients with type 1 diabetes reported fasting for at least 15 days during Ramadan in 42.8% of instances, whereas patients with type 2 diabetes reported doing so in 78.7% of cases. This includes diabetics who may have received advice to avoid fasting due to the risk of negative health effects [3].

Medication adherence is the act of taking drugs as prescribed and for the time period suggested by healthcare providers [4]. Non-adherence to medication leads to aggressive disease progression and higher treatment expenses; it is one of the difficult worldwide challenges [5, 6]. According to the literature, half of the patients with chronic diseases continue to take their medications improperly after a year of treatment, and this number rises to approximately 50% [7]. This non-adherence also causes comorbidities and disease-related consequences, which may lead to more frequent hospital admissions, emergency room visits, and direct treatment expenses. Depending on the country's healthcare system, either the health sector or, in some situations, the patient, may be responsible for covering these direct expenditures [8, 9]. For chronic conditions like type II diabetes mellitus (DM), which is characterized by fluctuating blood glucose levels, the issue of adherence to medications is crucial. This fluctuation can cause hyperglycemia or hypoglycemia [5]. Uncontrolled diabetes mellitus (DM) has been linked in studies to macro and microvascular problems and comorbidities, including hypertension, kidney problems, retinopathy, and, in rare cases, Parkinsonism [10, 11]. As a result, good disease management aids in achieving a healthy lifestyle [11]. The Kingdom of Saudi Arabia (KSA) has the second-highest prevalence of DM in the Middle East and ranks seventh globally [12]. In Saudi Arabia, a thorough epidemiological health research was conducted on persons aged 30 to 70 years who stayed in certain families. 4,004 of the 16,917 survey respondents - or approximately 23.7% of the population - had received a diagnosis of diabetes [13]. Other studies revealed higher prevalence with rates ranging from 26.0 to 61.8% [14, 15].

During the month of Ramadan, patients with diabetes mellitus in the KSA may exhibit reduced adherence to antidiabetic medications due to religious fasting observance, changes in daily routines, the influence of social and cultural factors, potential health consequences, inadequate awareness, and possible medication modifications. Understanding the dynamics of adherence to medication during Ramadan is crucial for healthcare providers and policymakers to develop targeted interventions that ensure the well-being of patients with diabetes during this significant religious period.

2. Methods

Study Design

This was a cross-sectional study designed to investigate medication adherence during Ramadan among patients with diabetes mellitus in the KSA.

Sampling Method

A convenience sampling method was used to recruit participants for the study. Participants were sourced from social media platforms, diabetes mellitus patient groups, and healthcare providers groups in Saudi Arabia.

Study population

We include adult population aged 18 years or above living in Saudi Arabia regardless their nationality. The study included participants who had a smartphone and access to the Internet. The sample size was established at 384 participants, determined based on a confidence level of 95% and a margin of error of 5%, supposing that 50% of the Saudi population with diabetes do not comply with their medication.

Data Collection

Data were collected using an online self-administered questionnaire designed to assess medication adherence during Ramadan. The questionnaire was made available to the participants for four weeks, corresponding to the duration of Ramadan. It consisted of two sections; the first, encompasses variables related to participants' region of residence (Aseer, Baha, Eastern region, Gouf, Hail, Jaan, Makkaha, Najran, Northern region, Qassim, Riyadh, Tabouk), gender (Female, Male), age groups (From 18 - 30 years, From 31-50 years, From 51-65 years, Above 65 years), type of diabetes (T1DM, T2DM), the recency of their last HbA1C test (More than a year, The last year, Within 3 months, Never), and HbA1c levels (between 6.4 - 5.7%, between 6.5 - 7.9%, between 8 - 9.9%, HbA1c 10 or more, Less than 5.7%, Never). The second section consisted of the Medication Adherence Rating Scale (MARS) a tool for assessing medication compliance. MARS offers a convenient and efficient means of assessing medication compliance in clinical settings due to its brevity, with only 10 binary (Yes or No) questions. Its ease of administration and interpretation make it a valuable tool for assessing medication adherence [16]. It is important to note that the use of an online self-reported questionnaire may introduce recall bias and social desirability bias.

Ethical Considerations

Informed consent was obtained from all participants before starting the questionnaire. Participants' privacy and confidentiality were strictly maintained throughout the data collection process. Ethical approval was obtained from relevant institutional review boards or ethics committees (UT-292-138-2023) in June ,5, 2023.

Data Analysis

We used R version 4.2 for statistical analysis. For normal distributed variables, quantitative data were presented as means with standard deviations (SD). Quantitative variables were described using number and percentage. Pearson's correlation was used to examine the relationship between compliance score and Hba1c level. An Analysis of Variance (ANOVA) test was used to analyze whether there are significant differences among the means more than two groups. A two-sample t-test was used to determine whether there was a significant difference between the means of two independent groups or samples. Multilinear regression models were used to assess the effect of different factors on the compliance score.

3. Results

Table 1 provides a comprehensive overview of the variables studied within the sample population of 384 individuals. Riyadh region (capital of KSA) had the largest representation, with 20.3% of the total sample, followed by the Makkah region at 14.1%. The gender distribution showed a relatively balanced representation, with 52.3% males and 47.7% females. Age categories were well-defined, ranging from above 65 years to 18-30 years, 31-50 years, and 51-65 years. T2DM was more prevalent in this sample, representing 64.1% of participants. The majority of participants had their HbA1c measured within the last three months (79.7%). Almost half of the participants (46.6%) had HbA1c levels between 8 and 9.9%.

Table 1: Demographic and diabetes-related characteristics of study participants

Studied variables	Overall (N=384)
Region	
Aseer	23 (6.0%)
Baha	24 (6.3%)
Eastern region	45 (11.7%)
Gouf	25 (6.5%)
Hail	22 (5.7%)
Jaan	21 (5.5%)
Makkaha	54 (14.1%)
Najran	21 (5.5%)
Northern Region	20 (5.2%)
Qassim	19 (4.9%)
Riyadh	78 (20.3%)
Tabouk	32 (8.3%)
Sex	
Female	183 (47.7%)
Male	201 (52.3%)
Age	
From 18 to 30 years	118 (30.7%)

	From 31-50 years	138 (35.9%)
	From 51-65 years	105 (27.3%)
	Above 65 years	23 (6.0%)
Type of Diabetes	T1DM	138 (35.9%)
	T2DM	246 (64.1%)
Last HbA1C	More than year	8 (2.1%)
	Never.	17 (4.4%)
	The last year	53 (13.8%)
	Within 3 months	306 (79.7%)
HbA1c	between 6.4 - 5.7%	44 (11.5%)
	between 6.5 - 7.9%	93 (24.2%)
	between 8 and 9.9%	179 (46.6%)
	HbA1c 10 or more	27 (7.0%)
	Less than 5.7%	24 (6.0%)
	Never	17 (4.4%)

The compliance score across various sociodemographic factors is depicted in table 2. The age group 51-65 years had the highest compliance score, 7.64 ± 1.71 while the age group from 31-50 years scored the lowest score 6.35 ± 1.64 , (p-value less than 0.001). There was no statistically significant difference in age between these two gender groups, as the p-value (0.380). There were no statistically significant differences in age among the regions, $p = 0.91$. The mean compliance score for Type 1 diabetes mellitus was 7.18 ± 2.40 while for Type 2 was 6.93 ± 1.71 the difference between the groups was 6.93 ± 1.71 , and the difference between the groups was not statistically significant $p = 0.2811$. The mean compliance score among individuals who did not fast, those who did not fast for one or more days, and those who fasted the entire month of Ramadan. The test statistic (29.95) and p-value (<0.001) indicate a highly significant difference in age between individuals who did not fast and those who fasted during Ramadan.

Table 2: compliance score across different sociodemographic factors

Variable	Mean \pm SD	Test statistics	P	
Age	From 18 -30 years	7.22 ± 2.38	9.577	< 0.001
	From 31-50 years	6.35 ± 1.64		
	From 51-65 years	7.64 ± 1.71		
	Above 65 years	7.17 ± 1.80		
Sex	Male	6.94 ± 1.85	0.88	0.380
	Female	7.11 ± 2.13		
Region	Aseer	7.30 ± 1.61	0.489	0.910
	Baha	7.00 ± 1.96		
	Eastern Region	6.89 ± 2.13		
	Gouf	6.88 ± 2.147		
	Hail	7.14 ± 2.19		
	Jazan	6.38 ± 3.0		
	Makkaha	7.19 ± 1.88		
	Najran	6.81 ± 1.72		
	Northern region	7.40 ± 1.76		
	Qassim	6.74 ± 2.16		
	Riyadh	7.0 ± 1.94		
	Tabouk	7.31 ± 1.97		
Fasting Ramadan	T1DM	7.18 ± 2.40	1.08	0.2811
	T2DM	6.93 ± 1.71		
	Did not fast	8.96 ± 0.98		
	One or more day	6.39 ± 2.21		
	Fast for all month	6.88 ± 1.84	29.95	<0.001

Figure 1 shows that there was a weak positive correlation between compliance and the HbA1C level $r = 0.098$, however, the p value was not statistically significant $p = 0.061$. Figure 2 shows a statistically significant association between compliance score and Hba1C Among male ($r = 0.35$, $p < 0.001$). However, this correlation was not proved among females figure 3.

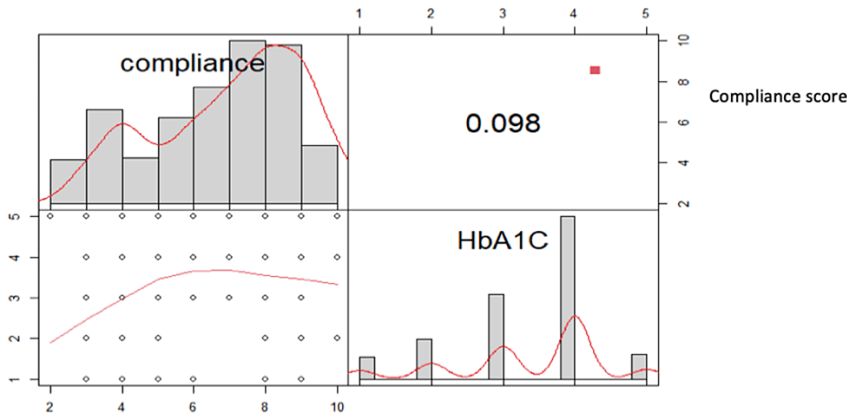


Figure 1: Correlation between HbA1C level and compliance to medication, the correlation is 0.098, \square means p-value = 0.061.

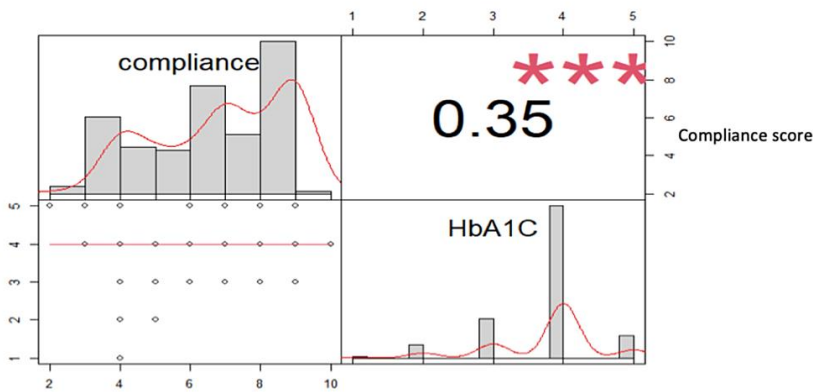


Figure 2: Correlation between HbA1C level and compliance to medication, the correlation is 0.35, *** means p-value < 0.001 (Males)

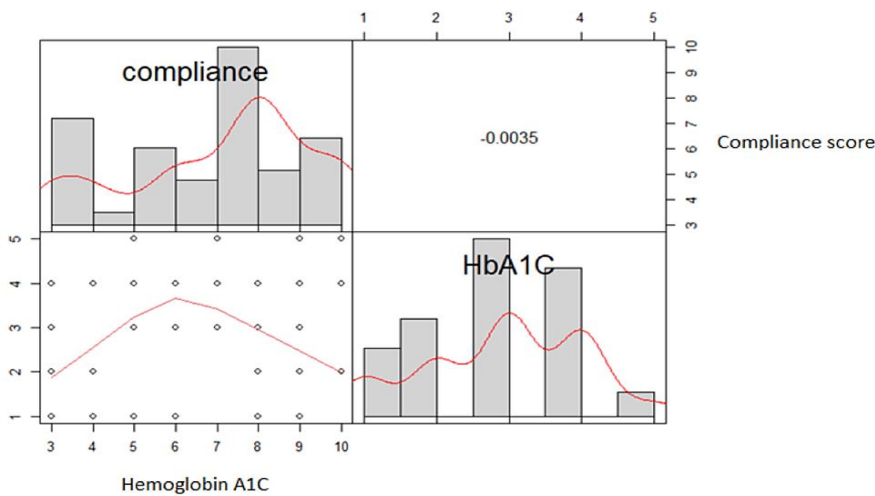


Figure 3: Correlation between HbA1C level and compliance with medication, the correlation is -0.0035 (weak negative correlation) and not significant (Females)

Table 3 presents the utilization of multilinear regression models to evaluate the influence of diverse factors on the compliance score. Age categories (31-50 years, 51-65 years, and older than 65 years) show varying effects

on compliance. Age between 31-50 years was negatively associated with compliance ($\beta = -1.06$, $p = 0.002$), while age between 51-65 years is positively associated ($\beta = 1.00$, $p = 0.003$). Age over 65 years does not have a significant impact ($p = 0.712$). Being male was negatively associated with compliance ($\beta = -0.72$, $p = 0.001$). Type of diabetes: The type of diabetes (T2DM) does not have a significant impact on compliance ($p = 0.388$). Different fasting behaviors like non-fasting one day or more ($\beta = -2.92$, $p < 0.001$) and fasting all month ($\beta = -2.90$, $p < 0.001$), with negative associations indicating lower compliance during fasting periods. Various HbA1c levels were significant predictors of compliance. Higher HbA1c levels were associated with increased compliance (e.g., HbA1c between 6.5 - 7.9%, $p < 0.001$).

Table 3: Multilinear regression models were used to assess the effect of different factors on the compliance score.

Studied variables	Beta	d. Error	t value	Pr(> t)
(Intercept)	7.39	0.82	8.986	< 0.001
Age (31-50 years)	-1.06	0.34	-3.14	0.002
Age (51-65 years)	1.00	0.34	2.95	0.003
Age (Above 65 years)	0.19	0.51	0.37	0.712
Sex (Male)	-0.72	0.22	-3.29	0.001
Region (Abha)	-0.85	0.50	-1.71	0.087
Region (Eastern region)	-0.26	0.43	-0.61	0.542
Region (Gouf)	-0.28	0.49	-0.57	0.568
Region (Hail)	-0.17	0.50	-0.33	0.740
Region (Jazan)	-0.86	0.51	-1.68	0.095
Region (Makkaha)	-0.21	0.42	-0.51	0.613
Region (Najran)	-0.09	0.51	-0.19	0.853
Region (Northern region)	0.26	0.51	0.52	0.607
Region (Qassim)	-0.61	0.53	-1.15	0.250
Region (Riyadh)	-0.10	0.40	-0.26	0.796
Region (Tabouk)	0.00	0.46	-0.01	0.994
Type of diabetes (T2DM)	0.29	0.34	0.87	0.388
Fasting (non-fasting one day or more)	-2.92	0.33	-8.83	< 0.001
Fasting (fast all month)	-2.90	0.37	-7.79	0.0001
HbA1c (6.4 - 5.7%)	1.05	0.45	2.35	0.019
HbA1c (6.5 - 7.9%)	2.69	0.46	5.91	0.0001
HbA1c (8 - 9.9%)	2.05	0.42	4.89	0.0001
HbA1c (10 or more)	2.23	0.56	4.01	0.0001
HbA1c (Never)	2.15	0.86	2.50	0.013
Last HbA1C test (last year)	0.98	0.68	1.45	0.148
Last HbA1C (Within 3 month)	0.75	0.64	1.17	0.242

4. Discussion

In this study we aimed to assess the compliance of patients with diabetes on hypoglycemic medication during the holy month of Ramadan in Saudia Arabia. The study's findings suggest that age has an impact on medication compliance, with varying effects observed among different age groups. Compliance tends to be lower in individuals aged 31-50 years, whereas those aged 51-65 years exhibit higher compliance. However, age over 65 years does not significantly influence compliance. Gender also plays a role, as being male is associated with lower compliance. Interestingly, T2DM does not seem to affect compliance significantly. Fasting behaviors, particularly nonfasting for one day or more and fasting for the entire month, were linked to lower compliance. Furthermore, higher HbA1c levels are associated with improved compliance, highlighting the importance of glycemic control in medication adherence.

Measuring diabetic patients' compliance

The following are the three fundamental measuring methods applied in psychiatric research. These include pill counts, biological assessments, and self-reports from patients and clinicians. Self-report methods are typically the least expensive and time-consuming option to get an indication of compliance. In this study, we used the

MARS questionnaire to assess patient compliance with medications during Ramadan. There are many tools to assess the compliance with treatment among patients. These tools show notable differences. For example, the Drug Attitude Inventory (DAI) primarily measures patients' attitudes and beliefs regarding their medication, relying on therapists' judgments for validation, and comprising 30 items. [17] In contrast, the Medication Adherence Questionnaire (MAQ) directly evaluates medication-taking behavior through four concise items and was validated based on a 5-year follow-up study correlating self-reported adherence with clinical outcomes. The Medication Adherence Rating Scale (MARS) aimed to address these differences by using item response theory (IRT) for development, emphasizing binary (Yes/No) responses, and including only 10 items, making it a more efficient and potentially more reliable method for assessing medication adherence, particularly among psychiatric patients. [18]

Factors associated with Compliance

Age: we found that the compliance score was significantly different across different age groups. After adjustment using multivariate analysis, we found that younger age categories were less compliant to medication compared to older age groups. Consistent with previous research that indicated that age is a significant factor in compliance with medication. Compliance was reported to increase with age, with the elderly group (over 55 years old), middle-age group (40-54 years old), and the young group (under 40 years old) being the main affected groups. [20] However, several researches found that getting older had the reverse effect on the cooperation of older people. [19, 20] Patients in these two age groups—patients who are middle-aged and younger patients under 40—actually constantly have other priorities in their everyday lives. They might not be able to attend treatment or have to wait a long time for appointments at the clinic because of their jobs and other obligations. This may explain the low compliance among these age category. [21]

Gender: The mean score of compliance was higher among females compared with males. We also found that the compliance score was significantly correlated with HbA1c among males not female. Regression analysis revealed that being male reduced the compliance score by 0.72. Research on gender differences in drug compliance remains ambiguous. It is recognized that among women, taking many drugs and ignoring the advice of medical professionals were significant factors behind not taking prescribed prescriptions. However, some data suggest that women are more likely than men to seek preventive care and treatment. [22] There may be gender-based variations in medicine adherence that affect the kind of diseases that men and women experience. Women are consistently less likely than men to take their diabetes and cardiovascular medications. [23]

Fasting in Ramadan: we found that people who did not fast in Ramadan had a higher compliance score compared to those who fasted. This difference remained statistically significant in multivariate regression analysis. Indeed, there is a gap regarding patient knowledge about fasting in Ramadan. A study in Eastern Saudi Arabia assessed the knowledge, attitude, and practice of 107 T2DM patients about fasting during Ramadan. The study found that sex, family history of diabetes, and education were independent determinants of the total score. The results suggest a significant knowledge practice gap in T2DM patients, highlighting the need for further strengthening of the Pre-Ramadan education program. [24] A study investigated the adherence of diabetes patients in the Tabuk region of Saudi Arabia to their prescribed medications and the association between adherence and other sociodemographic characteristics. The average adherence score to diabetes treatment was $9.6 \pm 3.3\%$, with 293 (77.1%) participants were adherent and 87 (22.9%) nonadherent. Forgetfulness was the most common cause of missed doses of medications and follow-up appointments. Sociodemographic factors such as marital status, nationality, geographic region, and occupation were significantly associated with treatment adherence. [25]

Association with HbA1C and compliance: we found a negative association between the last HbA1c level and the compliance score. Those who had a higher HbA1c reported a higher compliance score compared to those who had a lower HbA1c in the preceding months. This reflects the patient attitude to comply with medication after having high glycated hemoglobin measurement. On the other hand, a study in Saudi Arabia found a negative association between the last HbA1c level and the compliance score for patients with T2DM. Patients with higher HbA1c reported higher compliance scores, indicating a patient's attitude towards medication adherence. [26] We hypothesize that the discrepancy in the association between compliance and HbA1C is due to the fact that we relied on the most recent HbA1C measurements, which had a substantial positive impact on patient compliance.

Strengths and limitations

The study focuses specifically on the adherence to medications during Ramadan, which is a critical period for people with diabetes due to fasting practices. This targeted approach enhances the study's clinical relevance. The use of the Medication Adherence Rating Scale (MARS) was a strength, as it is a validated tool to assess compliance. However, the study had many limitations including that the use of convenience sampling may introduce selection bias, as participants were not randomly selected. Consequently, the findings may not be fully representative of the broader population of patients with diabetes mellitus in Saudi Arabia. Although the study includes participants from various regions and backgrounds, it is limited to individuals with access to smartphones and the Internet. This exclusion may not capture the experiences of those with limited access to technology. While we acknowledge that recruitment through social media may introduce some level of unreliability, we firmly believe that it remains a valuable avenue for reaching a diverse sample of participants. The study relies on self-reported data, which can be subject to recall bias and social desirability bias. Participants may provide answers that they believe are expected rather than reflecting their actual behaviors. Another limitation is the lack of investigation into the specific type and dose of anti-diabetic medication used by the participants. This omission hinders our ability to examine the potential impact of different medication types and doses on the observed outcomes.

5. Conclusions

The study's conclusions highlight several key findings regarding medication compliance among diabetes mellitus patients during Ramadan in KSA. Age emerged as a significant factor, with individuals aged 31-50 years exhibiting lower compliance, while those aged 51-65 years demonstrate higher compliance levels; age above 65 years does not significantly affect compliance. Gender also plays a role, as males were associated with lower compliance during Ramadan. Fasting behaviors, such as not fasting for one day or more and fasting for the entire month, significantly reduce compliance. Moreover, higher HbA1c levels were associated with improved compliance. These findings highlight the complex nature of Ramadan medication adherence and point to the necessity for patient-specific interventions and support plans to improve compliance, particularly during fasting periods, while taking patient demographics and glycemic control into account.

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