

Validity of the International Diabetes Federation risk stratification score of Ramadan fasting in individuals with diabetes mellitus

Eman M. Alfadhli, MD, Taif S. Alharbi, MD, Abrar M. Alrotoie, MD, Asia A. Aljohani, MD, Amal S. Qari, MD, Bashaer A. Alsubhi, MD, Aram H. Alsaedi, MD, Alaa A. Aljohani, MD.

ABSTRACT

الأهداف: لتقييم مدى صلاحية نظام تقييم الاتحاد العالمي للسكر الجديد لدرجة خطورة صيام رمضان للأشخاص المصابين بداء السكري.

المنهجية: أجريت دراسة وصفية وتقدمية خلال شهر رمضان المبارك 2022 في مركز السكر، مستشفى الملك فهد بالمدينة المنورة، المملكة العربية السعودية. تم استخدام نظام تقييم الاتحاد العالمي للسكر لدرجة خطورة صيام رمضان للأشخاص المصابين بداء السكري لحساب خطر الصيام على مرضى السكري. قُسم المرضى إلى 3 مجموعات: المجموعة الأولى عالية الخطورة، والمجموعة الثانية متوسطة الخطورة، والمجموعة الثالثة منخفضة الخطورة. تُرك قرار الصيام من عدمه إلى المرضى وأطبائهم المعالجين. خلال شهر رمضان تم متابعة المرضى وإعطائهم تعليمات بتسجيل قراءات السكر والأيام التي لم يكملوا صيامهم فيها وأسباب ذلك. وبعد شهر رمضان تم مقابلة المرضى مرة أخرى لمعرفة تجربتهم خلال صيام شهر رمضان المبارك.

النتائج: تم إدراج 466 مريض سكري، 79.4% مرضى السكري النوع الثاني و 20.6% مرضى السكري النوع الأول. بناءً على نظام تقييم الاتحاد العالمي للسكر لدرجة خطورة صيام رمضان للأشخاص المصابين بداء السكري (56.9%) 265 (56.9%) من المرضى صنفوا كمجموعة مرتفعة الخطورة للصيام، 115 (24.7%) متوسطي الخطورة، و 86 (18.4%) الأقل خطورة. أوضحت الدراسة أن عدم مقدرة المرضى على صيام كامل شهر رمضان المبارك يتوافق مع نتائج تقييم المرضى. كما أظهرت النتائج أن ذوي الخطورة المرتفعة من المرضى كانوا أكثر عرضة لارتفاع وانخفاض معدلات السكر في الدم مقارنة مع متوسطي وقليلي الخطورة. على الرغم من ذلك 53.2% من مجموعة الخطورة العالية، 70.4% من ذوي الخطورة المتوسطة كانوا قادرين على صيام كامل شهر رمضان المبارك.

الخلاصة: أوضحت الدراسة أن نظام تقييم الاتحاد العالمي للسكر لدرجة خطورة صيام رمضان للأشخاص المصابين بداء السكري فعال وقادر على إعطاء صورة تقريبية في تحديد مستوى الخطورة، مع ملاحظة أن بعض المرضى تم إعطائهم مستوى أكثر خطورة من الواقع.

Objectives: To assess the validity of the new International Diabetes Federation-Diabetes and Ramadan International Alliance (IDF-DAR) risk stratification tool for Ramadan fasting in predicting diabetic patients' ability to fast safely.

Methods: A prospective observational study was carried out during Ramadan 2022 at the Diabetes Center, King Fahad Hospital, Al-Madinah Al-Munawarah, Saudi Arabia. The IDF-DAR risk stratification tool was used to calculate fasting risk for diabetic patients pre-

Ramadan. The patients were allocated into 3 categories: high, moderate, and low risk. Fasting was left up to the patients and their healthcare providers. Participants filled out a log-sheet each day of Ramadan showing whether they completed the fast. A final interview was carried out after Ramadan to assess patients' fasting experiences.

Results: We included 466 patients with diabetes: 79.4% with T2DM and 20.6% with T1DM. Based on the IDF-DAR score, 265 (56.9%) patients were classified as high risk, 115 (24.7%) as moderate risk, and 86 (18.4%) as low risk. Non-fasting the whole month of Ramadan was statistically relevant to the IDF-DAR risk stratification score. High-risk individuals were more likely to experience hypoglycemia and hyperglycemia than those with a moderate or low risk. But overall, 70.4% of people at moderate risk and 53.2% of the ones at high risk observed Ramadan's complete fast.

Conclusion: The IDF-DAR has proven to be reliable and valid for predicting the risk of adverse events associated with fasting in diabetic patients. Nonetheless, it might overestimate the risk of fasting for some patients.

Keywords: Ramadan, fasting, diabetes mellitus, IDF-DAR risk stratification, validity

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From the Medical College (Alfadhli, Alharbi, Alrotoie, Asia Aljohani, Qari, Alsubhi, Alsaedi), Taibah University, from the Department of Internal Medicine (Alfadhli), King Faisal Specialist Hospital and Research Center, and from the Diabetes Center (Alaa Aljohani), King Salman Bin Abdulaziz Medical City, Al-Madinah Al-Munawarah, Kingdom of Saudi Arabia.

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Address correspondence and reprint request to: Dr. Eman M. Alfadhli, Medical College, Taibah University, Al-Madinah Al-Munawarah, Kingdom of Saudi Arabia. E-mail: emfadhli@taibahu.edu.sa
ORCID ID: <https://orcid.org/0000-0003-3842-4979>

For all adult Muslims, fasting during Ramadan is an obligation based on the 5 pillars of Islam. Patients with chronic illnesses and sick individuals for whom fasting threatens their health, including patients with diabetes, are exempt from fasting. Despite this, many patients ignore religious allowances along with medical advice and fast.¹⁻³ Therefore, knowing the actual risk of fasting and stratifying patients can provide appropriate advice on fasting and help with glycemic control, while also avoiding complications during Ramadan fasting.^{1,4,5}

The new International Diabetes Federation and the Diabetes and Ramadan International Alliance (IDF-DAR) risk stratification tool for Ramadan fasting system enables a more personalized risk assessment for diabetic patients considering the presence of 14 risk elements, such as diabetes complications, comorbidities, and other factors influencing fasting.⁶ Based on this score, diabetic patients will be categorized into low, moderate, or high risk. Fasting is safe for low-risk patients, not recommended for moderate-risk patients, and strongly discouraged for high-risk patients due to possible adverse effects.⁶

The reliability of this new scoring system has been assessed in a few studies.^{4,5,7-9} A recent study by Mohammed et al,⁴ from the United Arab of Emirates, assessed this score ability to predict the likelihood of patients with diabetes fasting and the risks from fasting, mostly type 2 diabetes mellitus (T2DM) patients (91.5%), and discovered that this tool correctly predicted both one's capacity to observe fasting during Ramadan and the tendency to develop hypo- or hyperglycemia. On the other hand, another study carried out at several diabetes clinics in Bangladesh with 1328 T2DM participants (the DAR-BAN study), concluded that this scoring system is more careful in how it categorizes T2DM patients' risks from fasting.⁵

More research is needed to refine the risk-scoring process to enable healthcare providers to make informed decisions regarding whether to allow patients to fast or not. We carried out the current study to determine whether the new IDF-DAR risk stratification score could foretell fasting abilities and associated risks from fasting in Saudi Arabian diabetic patients.

Methods. This was a prospective observational study conveyed at the Diabetes Center, King Fahad

Hospital, Al-Madinah Al-Munawarah, Saudi Arabia during Ramadan of 2022 (between February 2022 and June 2022). Patients with diabetes (T1DM or T2DM), aged ≥ 14 years who attended their routine diabetes follow-up at the center during 2 months before Ramadan of 2022, and who agreed to partake in the study were involved. Patients with any debilitating chronic diseases and pregnant women were excluded. The research ethics committee at Taibah University, College of Medicine, Al-Madinah Al-Munawarah, Saudi Arabia, approved the study. The study was carried out in agreement with the Declaration of Helsinki. After explaining the objective of the research to the patients and guardians of patients <18 years of age, consent was obtained.

Data were collected from the participants in 3 periods: within 2 months before Ramadan (period one), during Ramadan (period 2) and within 2 months after Ramadan (period 3).

Demographic data were collected from the participants during routine diabetes clinic visits within 2 months pre-Ramadan, which include age, gender, type and duration of DM, diabetes complications, and all other information that is required to calculate the IDF-DAR fasting risk score. Hemoglobin A1c (HbA1c), creatinine level, and estimated glomerular filtration rate were obtained from participants' electronic medical records. Afterwards, the online IDF-DAR risk stratification scoring tool was used to calculate the risk of fasting for each participant. Subsequently, patients were classified into 3 groups based on the IDF-DAR fasting risk score: high, moderate, and low-risk groups. Fasting was left up to the patient's preference and the healthcare provider's recommendation.

The participants were instructed to fill out a log sheet daily during the month of Ramadan to show whether they were able to complete the fasting of each day, the reason for breaking the fast, and the timing of breaking the fast. If the participant developed hypoglycemia or hyperglycemia, they had to document the blood glucose level. To ensure the accuracy of information, participants joined a WhatsApp group that reminded them to complete the sheet daily and answer their enquiries.

Ramadan daily assessment sheets were collected from the participants after Ramadan. Subsequently, the number of fasting days and days of breaking fast were calculated. In addition, the development of diabetic ketoacidosis (DKA), hospital admission (if any), and the reasons for admission were documented.

The association between IDF-DAR risk stratification score and the number of days of breaking the fast and hospital admission related to diabetes reasons/

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complications were compared between the 3 groups. Also, a comparison was carried out between T1DM and T2DM regarding IDF-DAR risk stratification and the ability to fast during Ramadan safely.

Statistical analysis. The Statistical Package for the Social Sciences, version 26 (IBM Corp., Armonk, NY, USA) program was used to analyze the data. Frequency and percentage were used to represent categorical data, whereas the arithmetic mean and standard deviation (SD) were used to explain quantitative continuous variables. The student's t-test was used to compare the mean of a continuous variable between 2 groups, and the Chi-square test was used to look into the relationship between the categorical variables. To determine the predictability of the IDF-DAR risk stratification score on the chance of not fasting the entire month of Ramadan, a binomial logistic regression was carried out. If the *p*-value was <0.05, the outcome was deemed significant.

Results. A total of 466 diabetic patients were included in the study: 196 (42.1%) males and 270 (57.9%) females, with a mean duration of diabetes 11.55±8.1 years. Most of the participants had T2DM 370 (79.4%) and 96 (20.6%) had T1DM. The mean age of T2DM participants was 55.4±11.9 years and the mean age of T1DM individuals was 24.2±8.1 years. Of the T1DM group, 4 patients were using insulin pump and 92 (95.8%) patients were on multiple doses of insulin. The frequency of hypoglycemic medications used in the T2DM group is shown in **Figure 1**. A total of 20 (4.3%) patients were advised not to fast pre-Ramadan by their healthcare personnel.

According to IDF-DAR risk stratification score; 265 (56.9%) of patients were categorized as having a high risk of fasting, 115 (24.7%) were moderate risk, and 86 (18.4%) were low risk. The sociodemographic characteristics of the entire sample and the 3 categories of risk groups are presented in **Table 1**. Patients from high-risk group tend to be younger, have higher HbA1c levels, suffer from T1DM more than T2DM, and have had diabetes for longer periods of time.

In total 168 (36.1%) patients did not fast the whole month of Ramadan and breaking the fast due to diabetes complications was the cause in 106 (22.4%) patients. There was a statistically significant association between IDF-DAR risk stratification score and non-fasting the whole month of Ramadan (*p*<0.001). Post hoc comparisons revealed a higher ratio of patients with high risk who did not fast the whole month of Ramadan compared to patients with moderate and low risk. Breaking the fast was more due to hypoglycemia than

hyperglycemia. Also, there was a significant association between admission to a hospital during Ramadan and IDF-DAR risk stratification (*p*=0.020). Post hoc comparisons disclosed higher rates of admission to the hospital among those with high risk compared to patients with low and moderate risk (**Table 2**).

Based on binomial logistic regression, patients with high risk were 6.69 times more likely than those with low risk and 2.09 times more likely than those with moderate risk not fasting the entire month of Ramadan. Also, patients with moderate risk have an odd ratio of 3.19 not fasting the entire month of Ramadan compared to patients with low risk (**Table 3**).

Table 4 demonstrates the association between diabetes type and IDF-DAR risk stratification and fasting during Ramadan. More patients with T1DM are categorized at a higher risk from fasting Ramadan than T2DM. The Post hoc comparisons revealed a higher ratio of patients with T1DM did not fast the whole month of Ramadan compared to patients with T2DM. Breaking fast was more frequent within the first 5 hours of fasting in the T1DM patients (**Figure 2**).

Discussion. In the current study, we found a greater proportion of high-risk categories (56.9%) and a lower proportion of low-risk categories. As opposed to our study, other studies found fewer high-risk categories and more low-risk categories.^{4,5} In Mohammed et al⁴ study, 22.3% of the participants were categorized as high risk, 26.3% as moderate risk, and 51.4% as low risk and in the DAR-BAN study, the frequency was 10.1% as high risk, 45.7% as moderate risk, and 44.2% as low risk.^{4,5} Perhaps this is because we had a higher percentage of T1DM patients in our study and the data were acquired from a diabetes center, where patients with uncontrolled diabetes and those suffering from diabetes complications usually receive care. Additionally, many T2DM participants in our study were taking sulfonylureas or insulin, which increase the fasting risk. Unsurprisingly, participants in the high-risk group had greater HbA1c levels and a longer duration of diabetes than patients in the moderate- and low-risk groups. As expected, T1DM was more prevalent in the high-risk group compared with T2DM and this explains why the high-risk group was younger than the moderate- and low-risk groups.

The present study aimed to investigate the validity of the 2021 DAR-IDF stratification score in correctly identifying those at risk from fasting.⁶ We found a statistically significant association between IDF-DAR risk categories and Ramadan fasting ability. Among patients at high risk, 31.7% did not fast the whole

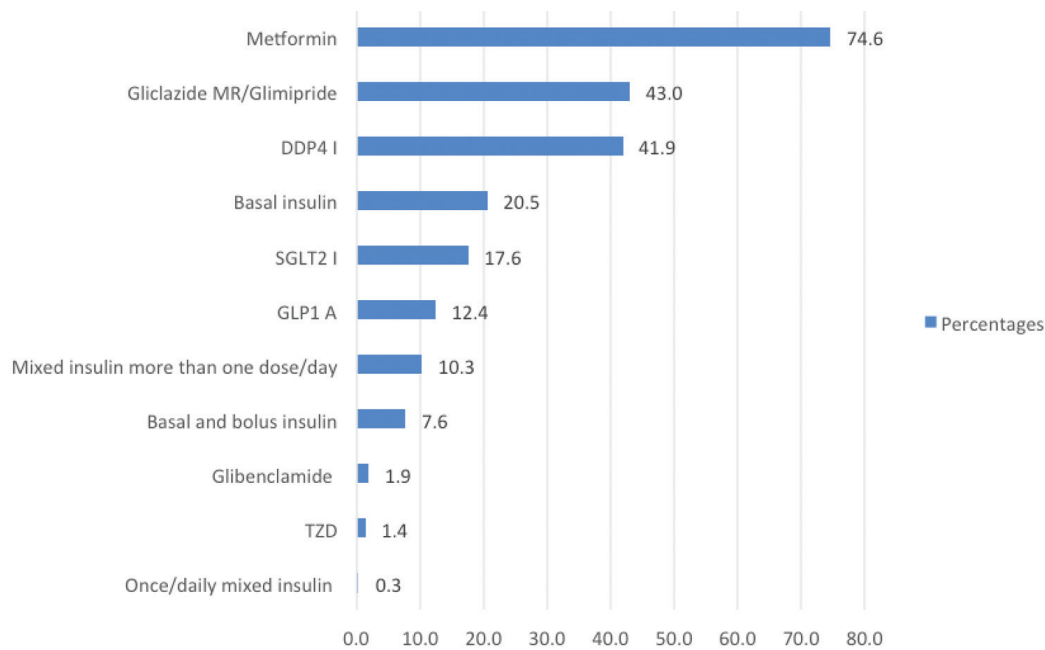


Figure 1 - Frequency of hypoglycemic medications use in type 2 diabetes mellitus group (n=370). DPP4: dipeptidyl peptidase-4 inhibitor, SGLT2I: sodium-glucose cotransporter-2, GLP1-A: glucagon-like peptide-1 agonist, TZD: thiazolidinediones

Table 1 - Baseline characteristics of the whole group and each risk group category (N=466).

Variables	All patients	IDF-DAR risk stratification			P-values
		Low risk (n=86)	Moderate risk (n=115)	High risk (n=265)	
Age (years)	49.0±16.9	53.8±13.1	48.7±15.5	47.5±18.3	0.011
HbA1c	8.7±1.8	7.6±1.5	8.8±1.7	9.0±1.7	0.000
e-GFR	93.2±30.1	87.21±26.7	94.5±26.9	94.6±32.3	0.115
Duration of diabetes (years)	11.6±8.2	7.3±5.5	10.0±7.9	13.6±8.3	0.000
Type 1 diabetes	96 (20.6)	2 (2.1)	13 (13.5)	81 (84.4)	0.000
Type 2 diabetes	370 (79.4)	84 (22.7)	102 (27.6)	184 (49.7)	0.000

Values are presented as numbers and percentages (%) or mean ± standard deviation (SD).
IDF-DAR: International Diabetes Federation-Diabetes and Ramadan International Alliance, HbA1c: hemoglobin A1c, e-GFR: estimated glomerular filtration rate

Table 2 - Association between International Diabetes Federation-Diabetes and Ramadan International Alliance risk stratification score and Ramadan fasting in individuals with diabetes (N=466).

Factors	All patients (N=466)	IDF-DAR risk stratification			P-values
		Low risk (n=86)	Moderate risk (n=115)	High risk (n=265)	
Fast all days of Ramadan	298 (63.9)	76 (88.4)	81 (70.4)	14 (53.2)	0.000
Did not fast the whole month of Ramadan	168 (36.1)	10 (11.6)	34 (29.6)	124 (46.8)	0.000
Diabetes related causes for non-fasting	106 (22.4)	4 (4.7)	18 (15.7)	84 (31.7)	0.000
Hypoglycemia	95 (20.4)	4 (4.7)	16 (13.9)	75 (28.3)	0.000
Hyperglycemia	27 (5.8)	1 (1.2)	4 (3.5)	22 (8.3)	0.023
DKA	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	0.684
Number of non-fasting days	3.01±6.7	0.63±2.0	2.03±5	4.2±8	0.000
Admission to the hospital during Ramadan	10 (2.1)	0 (0.0)	0 (0.0)	10 (3.8)	0.021

Values are presented as numbers and percentages (%) or mean ± standard deviation.
IDF-DAR: International Diabetes Federation-Diabetes and Ramadan International Alliance, DKA: diabetic ketoacidosis

Table 3 - Binomial logistic regression for the association between non-fasting all days of Ramadan and International Diabetes Federation-Diabetes and Ramadan International Alliance risk stratification score (N=466).

IDF-DAR risk stratification score	Odds ratio	P-values	95% CI	
			Lower	Upper
High risk versus moderate risk	2.09	0.002	1.31	3.34
Moderate risk versus low risk	3.19	0.003	1.48	6.90
High risk versus low risk	6.69	0.000	3.31	13.49

IDF-DAR: International Diabetes Federation - Diabetes and Ramadan Alliance,
CI: confidence interval

Table 4 - Association between diabetes type and International Diabetes Federation-Diabetes and Ramadan International Alliance risk stratification with fasting Ramadan (N=466).

Factors	Diabetes type		P-values
	T1DM (n=96)	T2DM (n=370)	
Age (years)	24.2±8.1	55.4±11.9	0.000
Duration of diabetes (years)	11.4±7.3	11.6±8.3	0.880
HbA1c	8.8±1.7	8.6±1.8	0.211
<i>IDF-DAR risk stratification</i>			
Low risk	2 (2.1)	84 (22.7)	0.000
Moderate risk	13 (13.5)	102 (27.6)	
High risk	81 (84.4)	18 (49.7)	
Fast all days of Ramadan	13 (13.5)	285 (77.0)	0.000
Did not fast the whole month of Ramadan	83 (86.5)	85 (23.0)	0.000
Diabetes related causes for non-fasting	59 (61.5)	4 (12.7)	0.000
Hypoglycemia	54 (56.1)	41 (11.1)	0.000
Hyperglycemia	18 (18.8)	9 (2.4)	0.000
DKA	1 (1.0)	0 (0.0)	0.050
Admission to the hospital	3 (3.1)	7 (1.9)	0.459
Breaking the fasting in the first 5 hours of the day	2.1±4.4	0.21±0.6	0.000
Breaking the fasting from 5 hours until 10 hours	1.02±2.1	0.84±2.1	0.600
Breaking the fasting after more than 10 hours	0.75±2.1	0.67±1.5	0.757

Values are presented as numbers and percentages (%) or mean ± standard deviation (SD).
T1DM: type 1 diabetes mellitus, T2DM: type 2 diabetes mellitus, HbA1c: hemoglobin A1c,
IDF-DAR: International Diabetes Federation - Diabetes and Ramadan Alliance, DKA: diabetic ketoacidosis

month of Ramadan due to diabetes-related factors, compared to 15.7% of moderate-risk patients, and 4.7% of low-risk patients. People with high risk are 6.7 times more liable to break the fast than those with low risk and 2.09 times more likely than those with moderate risk. When compared to patients with low risk, those with moderate risk have an odds ratio of 3.2 for not fasting the whole month of Ramadan. These results are consistent with those of the previous 2 studies.^{4,5} The prevalence of hypoglycemia was greater among individuals at high IDF-DAR risk (28.3%) than among those at moderate (13.9%) or low risk (4.7%). Furthermore, those at high risk had more episodes of hyperglycemia (16.3%) than those at moderate risk (3.5%) or low risk (1.2%). These results are in line

with those of the last 2 studies.^{4,5} There was also an association between Ramadan hospital admissions and the IDF-DAR risk category, with hospital admissions being higher among those with high risk as opposed to those with moderate or low risk. Furthermore, the number of non-fasting days was greater in the high-risk group compared with the moderate-risk and low-risk groups. The number of non-fasting days was 4.2±8 on average with a high risk, 2.03±5 in patients with a moderate risk, and 0.63±2.0 in patients with a low risk. It should be emphasized that 53.2% of patients in the high and 70.4% in the moderate risk categories, fasted safely the entire Ramadan month. Likewise, according to Mohammed et al,⁴ most diabetic patients (87%) fasted the whole Ramadan month, including

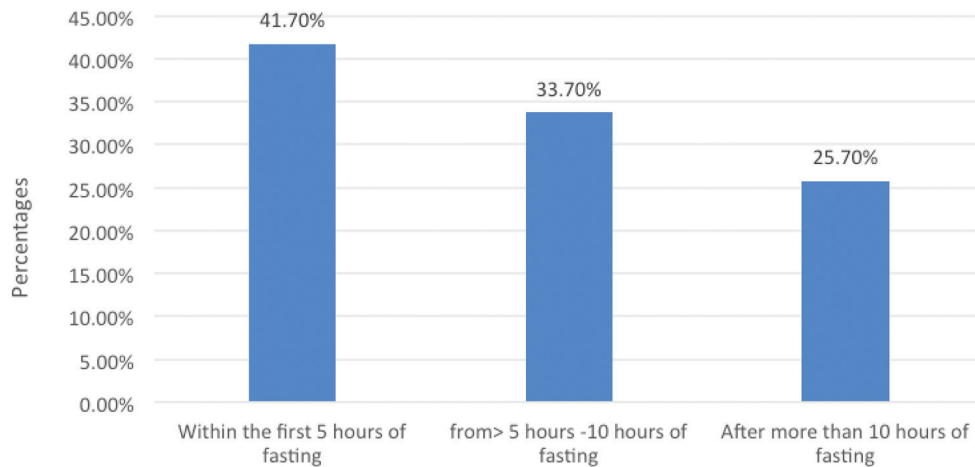


Figure 2 - Timing of breaking the fast.

76.9% of those in the high-risk group. Also, in the DAR-BAN study, all 30 days of Ramadan were observed by 71% of the participants; this included 72.8% of those in the moderate-risk group and 49.3% of those in the high-risk group.⁵ This suggests that the IDF-DAR stratification score might overestimate the risk of fasting in some diabetics. As Ramadan fasting is compulsory for all healthy adult Muslims, this tool must be fine-tuned to be able to identify patients at a real risk of fasting and avoid giving advice against fasting to patients who are safe to do so.

In the current study, 61.5% of T1DM patients needed to break their fast because of diabetes complications, contrasted with 12.7% of T2DM patients. In addition, hypoglycemia and hyperglycemia rates were more common in T1DM (56.1% versus 11.1%) than in T2DM (18.8% versus 2.4%). Obviously, this is a result of insulin therapy for T1DM, which increases hypoglycemia and hyperglycemia risks. The IDF-DAR categorizes T1DM patients as having a moderate-to-high fasting risk. For example, those with controlled T1DM for less than 10 years and no complications receive a minimum score of 5.5. Evidence from many previous studies suggests that some T1DM patients can fast safely during Ramadan when they follow medical advice.¹⁰⁻¹²

With the new IDF-DAR stratification score, practitioners can more easily assess fasting risks in diabetic patients. However, it appears that our cohort's healthcare provider did not take advantage of this score, as only 20 patients were advised not to fast, despite 56.9% of them being at high risk and 24.7% at moderate risk. Healthcare professionals may not be aware of the score or may not have time to apply it to

every patient in a busy clinic. Per IDF-DAR guidelines, diabetic patients should be educated on safe fasting within 2 months of Ramadan and assessed for their risks from fasting.⁶ In real practice, this may not be feasible since medical systems cannot accommodate seeing all diabetic patients within 2 months before Ramadan. In addition to Ramadan, some Muslims fast regularly on Mondays and Thursdays of each week, or 3 days a month. It is therefore essential to provide ongoing education regarding safe fasting during routine clinical visits.

The most popular time to break the fast in patients with T1DM was in the early hours after fasting, such as, the first 5 hours of fasting (41.70%), compared to the pre-Iftar hours (25.70%). Failure to reduce the dose of the rapid- or short-acting insulin before the Suhoor meal could be the reason. The finding was consistent with those of a prior study, which shown that hypoglycemia that necessitates breaking of the fast is more likely to occur in the first few hours of fasting in Saudi Arabian patients as opposed to patients from other countries.¹³

Study limitations. The main limitation of the present study is that it is from a single diabetes center, so it may not be representative of all diabetic patients. However, our study represents one of the very few studies that assessed the validity of the new IDF-DAR risk calculator for Ramadan fasting. Another point of the study's strength lies in its prospective nature and following participants daily throughout the month of Ramadan, so information such as episodes of hypoglycemia, hyperglycemia, and the time of breaking the fast is more reliable than in other studies which relied solely on patient recalls after Ramadan. In addition, our study distinguished between diabetes-related causes

of non-fasting and non-diabetes-related causes, which correctly reflects the risk of fasting for diabetic patients.

In conclusion, based on the findings of this study, the newly IDF-DAR scoring system is valid for categorizing diabetic patients' risks regarding fasting complications. However, it may overestimate the risk of fasting in some patients. Further research should focus on improving the accuracy of the IDF-DAR scoring system.

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