diabetesresearchandclinicalpractice211(2024)111661

Contents lists available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.journals.elsevier.com/diabetes-research-and-clinical-practice

Verification of 2021 IDF-DAR risk assessment tool for fasting Ramadan in patients with diabetes attending primary health care in The Kingdom of Bahrain: The DAR-BAH study

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A B S T R A C T

Background: There is a high prevalence of diabetes mellitus among Muslim adult patients. Those Muslims are required to fast the holy month of Ramadan. However, the Islam religion exempted some people with medical issues. It was not clear if all the patients with diabetes were considered medically unfit to fast Ramadan. Therefore, IDF-DAR group created a new risk calculator to categorize the patients with diabetes to advise with or against fasting accordingly.
Objective: This study is validating the IDF-DAR tool in assessing the accuracy of IDF-DAR risk calculator tool on adult patients with diabetes visiting primary health care in the Kingdom of Bahrain. The study will facilitate the health care professionals' decision to exempt the patients from fasting.
Methods: It is a prospective, randomized study for Ramadan 1444/2023 to assess the new IDF-DAR risk score tool that predicts the complications and the negative outcome of fasting during Ramadan. It included pre- and post-Ramadan questionnaires. 757 patients were selected randomly from the patients list of the central diabetes clinics in primary health care for pre-Ramadan risk assessment scoring. Post-Ramadan a phone a questionnaire was done to evaluate the ability of fasting and the occurrence of adverse events.
Results: Out of the 757 participants, 611 were included in the study. The mean age of the studied population was 59.8 years and 52.8 % of them were female. 630 (95.3 %) had type 2 diabetes. According to the new IDF-DAR risk calculator, 184 (27.8 %) were categorized as low risk ($\leq$3 score), 252 (38.1 %) as moderate risk (3–6 score), and 225 (34 %) as high risk (>6 score). The percentage of patients completed their 30 days fasting successfully without reporting adverse events in the low, moderate, and high-risk groups were 92.4 %, 89.3 %, 74.7 % respectively. There was significant increased risk in breaking the fast between the low-risk group and high-risk group with a p-value of <0.001. Similarly, there was significant increased risk in breaking the fast between the moderate-risk group and high-risk group with p-value of <0.001. The main reason of breaking the fast was hypoglycemic attacks. The leading factors that play a significant role in increasing the risk of adverse events during fasting Ramadan were type 1 diabetes mellitus, the presence of previous hypoglycemia attacks, the presence of renal impairment, and negative previous Ramadan experience.
Conclusion: The new IDF-DAR risk calculator is a good tool to predict both the ability to fast Ramadan and the probability of experiencing adverse events (mainly hypoglycemia) in people with diabetes mellitus in Kingdom of Bahrain.

1. Introduction

Diabetes Mellitus is increasing globally, with a prevalence of more than 451 million and an expected rise reaching 693 million individuals in 2045 [1]. Additionally, statistics reveal that more than 90 million Muslims have diabetes worldwide [2]. According to Muslim rules, five pillars are obligatory for each Muslim to practice in his/her adult life unless exempted due to certain exceptions such as illnesses. Fasting during the holy month of Ramadan is one of these five pillars that all Muslims are keen to implement yearly. It is implemented by abstaining from food, drink, medications, and anything ingested orally from pre-dawn to sunset, translating to around 12–18 h of fasting daily for 29–30 consecutive days [3].

These prolonged fasting hours may lead to a metabolic disturbance, increasing the risk of diabetic ketoacidosis, dehydration, thrombosis, hypoglycemia, and hyperglycemia in patients with diabetes. For instance, in the EPIDIAR study, the risk of severe hypoglycemia significantly increased in type 1 and type 2 diabetes mellitus. Although, Islam's rule exempts some people with medical illnesses from fasting during Ramadan, the EPIDIAR study found that during Ramadan, a

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https://doi.org/10.1016/j.diabres.2024.111661
Received 19 February 2024; Received in revised form 29 March 2024; Accepted 4 April 2024
Available online 10 April 2024

substantial proportion of individuals with diabetes fasted Ramadan. Specifically, the study reported that 42.8 % of patients with T1DM and 78.7 % of those with T2DM fasted for at least 15 days [4,5]. Conversely, Baynouna AlKetbi et al. did not observe significant adverse events among individuals at high risk, particularly those with chronic kidney disease, when fasting [6]. To address these concerns, the International Diabetes Federation-Diabetes and Ramadan (IDF-DAR) group created a risk score calculator to facilitate the stratification of diabetic patients into three main categories: low, moderate, and high-risk groups with a higher risk of hypoglycemia and hyperglycemia in the high-risk category compared with the others. Several factors might increase the risk of complications in stressful events such as fasting for many hours, including the type of diabetes, the treatment used, macrovascular disease, renal function, and hypoglycemia risks, among others [7,8].

On a positive note, a *meta*-analysis showed that patients with type 2 diabetes significantly reduced HbA1c and fasting blood glucose after fasting during Ramadan compared to pre-Ramadan values [9]. Furthermore, Ramadan fasting has a non-significant determinant effect on the deterioration of renal function and is not related to adverse events in patients with chronic kidney disease, as observed in the Diabetes Control During Ramadan Fasting study [10]. Additionally, the incidence of cardiac events was similar during fasting Ramadan compared with non-fasting days in a recent validation study [11].

A second study evaluated the applicability of the risk score on Bangladeshi people with diabetes mellitus to demonstrate their experience with the IDF-DAR risk calculation score. The study showed that 71 % of their patients successfully fasted the whole month, despite falling into the high-risk category. Individuals during Ramadan experienced a 3.74-fold increase in the risk of hypoglycemia and a 3.86-fold increase in the risk of hyperglycemia [12].

Furthermore, another study conducted during Ramadan and Dhu Al-Qi'dah Months showed contradictory results. The analysis demonstrated no statistically significant differences in the reasons for admission, length of hospital stays, or hospital mortality between the two months. This implies similar rates of diabetic complications during both fasting and non-fasting periods. Importantly, these results also affirm the safety of fasting, highlighting no notable concerns regarding the well-being of individuals practicing fasting in the context of diabetic management [13].

To our best knowledge, no study has evaluated the accuracy of categorizing the patients' risk of fasting during Ramadan using the new IDF-DAR risk calculator on patients with diabetes in the Kingdom of Bahrain. Therefore, this study aims to validate the recent IDF-DAR risk stratification score among patients with diabetes in Bahrain.

2. Subjects, materials and methods

2.1. Study design

This study is a prospective non-interventional Cohort study. It involved patients in primary care diabetes clinics, where patients were evaluated routinely for fasting safety during Ramadan and receive advice on whether to fast or not according to their IDF-DAR risk score. The score categorizes the patients with diabetes as low, moderate, or high-risk. The primary health care ethical committee granted the ethical approval to conduct the research.

2.2. Study population

A total of 757 patients were randomly selected from the patient list of the central diabetes clinics (CDC) in primary health care for pre-Ramadan assessment. Among these, 611 participants met the inclusion criteria and were included in the study. Inclusion criteria encompassed adult patients aged > 18 years with diabetes undergoing routine follow-up at the CDC. These patients were assessed for the safety of fasting using the IDF-DAR risk assessment score and expressed the intention to fast during Ramadan. Conversely, the study excluded patients who, during the post-Ramadan phone interview, declared the decision not to fast, were unreachable, or refused to participate in the call.

3. Methods

In the initial phase of the methodology, a systematic random sample was chosen from the electronic medical records (I-SEHA) across 11 health centers in Bahrain. This selection process involved randomly choosing the first patient from the initial five listed patients and subsequently including every fifth patient thereafter. Concurrently, the physician utilized the IDF-DAR risk assessment tool to guide patients on their eligibility for Ramadan fasting. This tool was employed to make necessary medication adjustments and offer general advice to minimize associated risks. The risk assessment tool incorporates 14 key items, encompassing considerations such as diabetes type and duration, level of glycemic control, history of hypoglycemia, self-monitoring of blood glucose (SMBG) practices, types of glucose-lowering medications, presence of acute diabetes complications like Diabetic Ketoacidosis (DKA) and Hyperglycemic Hyperosmolar Non-Ketotic Coma (HONC), macrovascular complications, and chronic kidney disease (CKD). Additionally, it includes factors such as pregnancy status, frailty, cognitive function, physical labor, fasting hours, and previous Ramadan experience. Each question in the tool is assigned a specific score [8]. Subsequently, based on the sum of all items in the IDF-DAR assessment tool, the study subjects are classified as low, moderate, or high risk for fasting during the Holy month of Ramadan. Those who scored > 6 were considered to be at high risk, and it was strongly advised that they refrain from fasting. Meanwhile, those scoring from 3.5 to 6 were considered moderate-risk and advised against fasting or with caution. Patients with a score ≤ 3 were considered low risk and permitted to fast [8].

Following this thorough risk assessment, eligible patients were identified, and a phone interview was conducted after Ramadan to evaluate their fasting experience, with a particular focus on medication adjustments and adherence to provide advice. Verbal consent for study participation was obtained from the selected patients. Importantly, patients were interviewed both before Ramadan, during which they were assessed, provided with a score, and given advice for or against fasting. They were subsequently re-interviewed by phone post-Ramadan, addressing specific questions related to their fasting experience.

IDF DAR assessment tool risk score is displayed in Appendix 1.

Post Ramadhan assessment questionnaire is displayed in Appendix 2.

3.1. Statistical analysis

The data entry and analysis were conducted using SPSS 26 software. For categorical variables, frequencies and percentages were computed, while quantitative variables were described using mean, standard deviation (SD), median, and interquartile range (IQR). The Chi-square test was employed to assess significant differences in the percentage of patients breaking their fast among low, moderate, and high-risk groups. Additionally, the Chi-square test was used to determine significant differences in the percentage of patients experiencing adverse events within these risk groups. Another Chi-square test was applied to compare the incidence of breaking the fast between patients with uncontrolled and controlled HbA1c among those on insulin therapy.

To evaluate mean differences in risk scores, an independent samples *t*-test was performed between participants who broke their fast and those who did not. Spearman's rho correlation was utilized to explore the relationship between the number of days the fast was broken and the risk score. Prevalence odds ratios of adverse events were calculated for high and moderate-risk groups compared to the low-risk group among participants who broke their fast. Binary logistic regression analysis was employed to investigate the risk factors predisposing diabetic patients to break their fast during Ramadan. Normality of risk scores for

participants who broke and did not break their fast was assessed using the Kolmogorov-Smirnov Test.

4. Results

The authors invited 757 participants to be involved in the study. However, 39 patients (5 %) didn't respond. Of those remaining, 57 patients were excluded from the study because they stated not fasting Ramadan during the phone interview. Therefore, the analysis included 661 participants.

The mean age of the participants was 59.8 (SD = 11.9) years and 52.8 % of the patients were females. No pregnant patients were included, and all patients fasted for less than 16 h.

According to self-reported outcomes, the majority of the study population had a prolonged duration of uncontrolled Type 2 diabetes and on one or more hypoglycemic therapy. The patients with Type 2 diabetes mellitus were (630; 95.3 %) of the population. Patients suffering from diabetes mellitus for 10 years or more were 479; 72.5 %). Most of the patients denied hypoglycemia in pre-Ramadan assessment (475; 71.9 %). Only (214; 32.4 %) patients had pre-Ramadan HbA1c < 7.5 %. The study sample were on different type of therapies. Those on multiple daily mixed insulin injection were (135; 20.4 %), basal Bolus (104; 15.7 %), only (12; 1.8 %) patients were on mixed once daily insulin, those on basal insulin were (134; 20.3 %) patients, on insulin secretagogues were 229 patients (34.7 %), and only (47; 7.1 %) patients were on other therapy not including SU or insulin.

Most of the patients stated conducting self-monitoring of blood glucose as indicated (501; 75.8 %). Most of the patients reported no DKA or HONC (650; 98.3 %). Moreover, most of the studied population didn't have cardiovascular or renal complications (581; 87.9 %) and (555; 84 %) respectively. Most of the patients were not having cognitive impairment or frailty (645; 97.6 %). Most of the patients have no physical labour 598 (90.5 %). Lastly, Table 1 demonstrated (53; 8 %) patients with overall negative experience during fasting the previous Ramadan (see Fig. 1 and Table 2).

The mean (SD) risk score of the participants according to the current IDF-DAR risk assessment tool is 5.3 (3.3). The data of this study also revealed that more than two-thirds of the patients (477; 72.2 %) fall into the moderate (252; 38.1 %) or high-risk categories (225; 34 %), as shown in Fig. 2.

Among the 661 participants, (563; 85 %) fasted all Ramadan, whereas (98;15 %) patients to break their fast at least one day. Among the subset of 98 patients who confirmed breaking their fast, the mean number of days for those who had to break their fast was 5.4 (SD 6.4). The mean number of breaking fast days were almost similar between the risk categories: high-risk 4.1 (6.5), moderate-risk 6.1 (6.7) and high-risk 5.4 (6.4). It is noticeable the high standard deviation of the previous results reflecting wide distribution of values Table 3. The main reason for breaking the fast was hypoglycemia (63;64.3 %), only (13;13.3) patients reported breaking their fast due to hyperglycemia, other reasons such as infections in (35;35.7 %) patients. Most of the patients confirmed their hypoglycemia or hyperglycemia events by home glucose monitoring (56;88.9 %) and (11;84.6 %) respectively.

The participants who broke their fast had a mean score of 7 (SD = 3.4), while those who safely observed fasting during Ramadan had a mean score of 5 (SD = 3.1). The observed difference is statistically significant, indicated by a P-value of less than 0.001. Furthermore, the percentage of patients breaking their fast in the low-risk category was only 7.6 %, while the percentage of breaking the fast in the high risk category was significantly higher (25.3 %). Therefore, high-risk groups are more likely to break their fast compared to those in the low and moderate risk groups. Notably, breaking the fast is proportionate to the risk level, with higher risk levels correlating to a greater likelihood of breaking the fast (high > moderate > low). Statistical analysis indicates a notable distinction between the low-risk group and high-risk group (P < 0.001), as well as a statistically significant difference between the moderate-risk group and high-risk group (p < 0.001). Importantly, the results indicate that the risk of experiencing adverse events is 7.7 times higher in the high-risk subjects compared to their low-risk counterparts Fig. 3.

Binary logistic regression of risk factors on breaking fasting during Ramadan revealed that Type 1 diabetes (p-value 0.027), presence of hypoglycemia (p-value 0.012), presence of renal impairment (p-value 0.031) and negative previous Ramadan experience (p-value < 0.001) significantly increases the risk of breaking the fast-during Ramadan due to adverse events. Whereas the other elements such as the duration of diabetes (p-value 0.089), level glycemic controlled (p-value 0.318) and insulin therapy (p-value 0.071) and hypoglycemia inducing oral therapy (p-value 0.881) as type of treatment didn't increase the risk of breaking the fast-during Ramadan, Table 4.

Table 1
Baseline risk elements among the subjects in the study.

	Subgroup	Number (%)
Diabetes type	Type 1 DM	31(4.7)
	Type 2 DM	630 (95.3)
Duration of Diabetes	≥10 years	479 (72.5)
	<10 years	182 (27.5)
Presence of hypoglycaemia	Hypoglycaemia unawareness	4 (0.6)
	Recent Severe hypoglycaemia	6 (0.9)
	Multiple weekly Hypoglycaemia	49 (7.4)
	Hypoglycaemia less than 1 time per week	127 (19.2)
	No hypoglycaemia	475 (71.9)
Level of glycaemic control	HbA1c levels > 9 % (>75 mmol/mol)	155 (23.4)
	HbA1c levels 7.5–9 % (58–75 mmol/mol)	292 (44.2)
	HbA1c levels < 7.5 % (<58 mmol/mol)	214 (32.4)
Type of treatment	Multiple daily mixed insulin Injections	135 (20.4)
	Basal Bolus/Insulin pump	104 (15.7)
	Mixed Once daily insulin	12 (1.8)
	Basal Insulin	134 (20.3)
	Insulin secretagogues	229 (34.7)
	Other therapy not including SU or Insulin	47 (7.1)
Self-Monitoring of Blood Glucose (SMBG)	Indicated but not conducted	46 (7)
	Indicated but conducted sub-optimally	114 (17.2)
	Conducted as indicated	501 (75.8)
Acute complications	DKA/ HONC in the last 3 months	1 (0.2)
	DKA/ HONC in the last 6 months	3 (0.5)
	DKA/ HONC in the last 12 months	7 (1.1)
	No DKA or HONC	650 (98.3)
MVD Complications/ Comorbidities	Unstable MVD	12 (1.8)
	Stable MVD	68 (10.3)
	No MVD	581 (87.9)
Renal Complications/ Comorbidities	eGFR < 30 mL/min	9 (1.4)
	eGFR 30–45 mL/min	28 (4.2)
	eGFR 45–60 mL/min	69 (10.4)
	eGFR > 60 mL/min	555 (84)
Frailty and Cognitive function	Impaired cognitive function or Frail	6 (0.9)
	>70 years old with no home support	10 (1.5)
	No frailty or loss in cognitive function	645 (97.6)
Physical Labour	Highly Intense physical labour	2 (0.3)
	Moderate Intense Physical Labour	61 (9.2)
	No physical labour	598 (90.5)
Previous Ramadan Experience	Overall negative experience	53 (8)
	No negative or positive experience	608 (92)

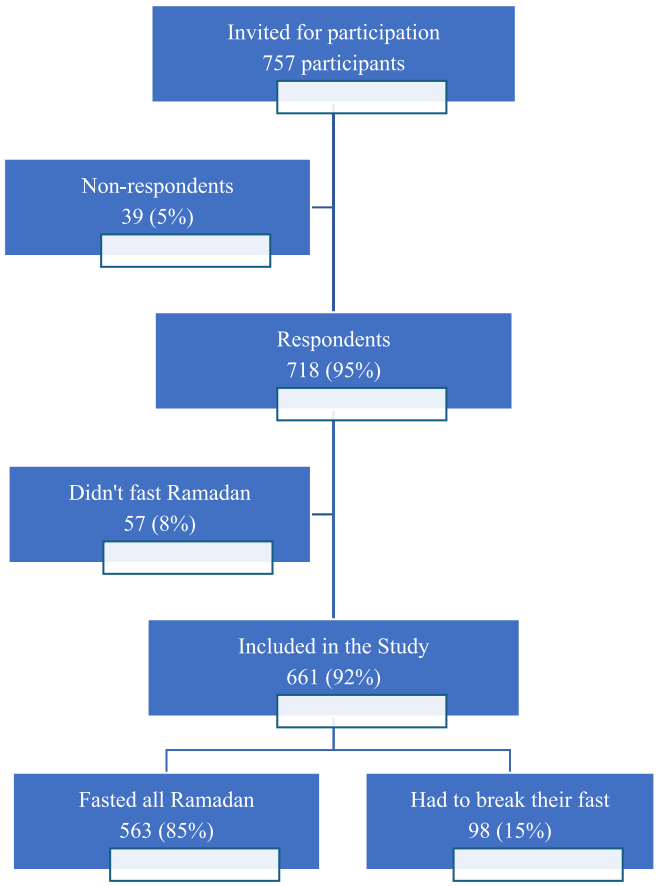

Fig. 1. Flow diagram for study participants.

Table 2
Descriptive statistics of the variables concerning fasting in Ramadan.

Variables	n (%)
Are there any days that you had to break your fast during Ramadan? (Total = 661)	
Yes	98 (14.8)
No	563 (85.2)
How many days did you have to break your fast? (Total = 98)	
Median (IQR)	3 (6)
Mean (SD)	5.4 (6.4)
What is/are the reasons for breaking your fast during Ramadan? (Total = 98)	
Hypoglycemia reason for breaking your fast	63 (64.3)
Hyperglycemia reason for breaking your fast	13 (13.3)
Other reasons	35 (35.7)
In case of breaking your fast due to hypoglycemia, did you confirm it by measuring your blood glucose at home? (Total = 63)	
Yes	56 (88.9)
No	7 (11.1)
In case of breaking your fast due to hyperglycemia, did you confirm it by measuring your blood glucose at home? (Total = 13)	
Yes	11 (84.6)
No	2 (15.4)

The type of treatment was studied individually as it is known that hypoglycemic agents might increase the occurrence of hypoglycemic events and therefore the incidence of breaking the fasting during Ramadan. It was found that only (30; 22.2 %) of those on multiple daily mixed insulin injections reported breaking their fast at least 1 day. Similarly, (27; 26 %) patients on basal bolus had to break their fast. Moreover, low percentage of those on once daily mixed insulin or basal insulin had to break their fast (2;16.7 %) and (17;12.7 %) respectively. The 4 participants who were on glibenclamide reported fasting safely. The number of participants on Gliclazide and broke their fast were (18; 8 %). Lastly. (4;8.5 %) reported breaking their fast while they were on other therapy not including SU or insulin, Table 5.

5. Discussion

This research involved 661 Muslim patients diagnosed with diabetes, who sought pre-Ramadan assessments in 2023. These individuals were attending the central diabetes clinics in the primary health care system in the Kingdom of Bahrain. The purpose of the assessments was to evaluate their readiness to fast during Ramadan. Most of our patients are in the moderate and high risk (72.2 %). These results align closely with those reported in the DAR-BAN study (55.8 %) [12], which similarly involved patients fasting during Ramadan after receiving pre-Ramadan counselling from their Diabetologist about the associated risks, mirroring the approach taken in the DAR-BAN study.

Similar to findings in comparable studies, it is observed that individuals in the high and moderate-risk categories face a significantly greater likelihood of breaking their fast due to adverse events, such as hypoglycemia or hyperglycemia, compared to those in the low-risk group [11]. There is a 7.7-fold increase in the risk of adverse events during Ramadan fasting compared to patients in the low-risk group. These consistent findings suggest that the new IDF-DAR risk calculator accurately predicts the risk for this population during the fasting period.

This study aimed to investigate fasting practices during Ramadan 2023. Interestingly, our findings align with the DAR-BAN study, indicating that most participants in the moderate (89.3 %) and high-risk (74.7 %) groups successfully completed the entire 30 days of fasting without experiencing adverse events such as hypoglycemia that would necessitate breaking their fasts.

The high-risk group may opt to fast for the majority of the month, underscoring the need to embrace and support individuals with chronic diseases or other circumstances who wish to participate in fasting to the best of their ability. Recognizing that fasting on some or most days holds significant importance for many, including those with diabetes or other chronic conditions, pre-Ramadan consultations and support is imperative to discuss potential harms, medication adjustments, and risk mitigation strategies as well as clear guidance on sick day rules to ensure safe fasting practices. This could involve advocating for rest days if there are indications that fasting could compromise health. Moreover, healthcare professionals are advised to make shared decisions with patients on whether to fast, safe medication administration, reducing dehydration risk, and ensuring adequate nutrition.

It's essential to acknowledge the limitations of the risk scoring system, which primarily offers binary options (fasting vs. non-fasting for the entire month) and overlooks the concept of intermittent fasting. Intermittent fasting is a flexible approach and valid religious option for some individuals and should be taken into account within the framework of supporting diverse religious practices and beliefs [14].

The generally low hypoglycemia rate can be attributed to the high levels of glycated hemoglobin before Ramadan, signifying inadequate glycemic control and a reduced vulnerability to hypoglycemic attacks. Another explanation for these intriguing findings is the uneven weighting of the factors in the risk calculator. This suggests that certain factors may have a varied impact on breaking the fast compared to what was initially predicted.

The results suggest that Type 1 Diabetes, the presence of hypoglycemia, renal impairment, and a negative previous Ramadan experience are linked with a higher risk of developing adverse events and breaking the fast-during Ramadan. These factors were statistically significant, although they represent the minority of the studied population. On the other hand, a prolonged duration of uncontrolled type 2 diabetes is not associated with a high incidence of adverse events.

Furthermore, over half of the study sample was undergoing insulin therapy (58.2 %), yet the majority observed fasting throughout the

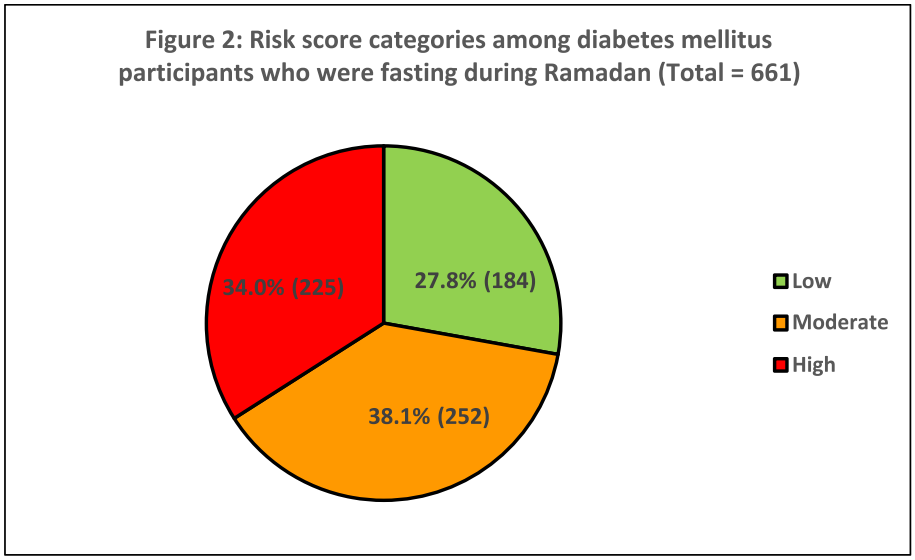

Fig. 2. Risk score categories among diabetes mellitus participant who were fasting during Ramadan (Total = 661).

Table 3
Number of breaking fast days according to Risk categories (Total = 98).

Risk categories	Number of breaking fast days	
	Mean ± SD	Median (IQR)
Low	4.1 ± 6.5	2 (2)
Moderate	6.1 ± 6.7	3 (9)
High	5.4 ± 6.3	3 (6)
Total	5.4 ± 6.4	3 (6)

entire Ramadan without breaking it for even a single day (80.6 %). A plausible interpretation of these findings is that a significant proportion of the included sample had poorly controlled conditions. Consequently, there exists an opportunity to safely adjust insulin therapy, given the ample time available before the patient reaches the hypoglycemic state. This justification should be interpreted with caution because it couldn't be proved statistically, and the hypoglycemia attacks are unpredictable even in patients with poor glycemic control proved by high glycated haemoglobin due to glucose variability [15]. Nonetheless, studying the factors such as the compliance to the insulin therapy that contribute to poor glycemic control in our patients is outside the scope of this study.

The subjects, averaging nearly 60 years old, exhibit surprisingly low rates of macrovascular and microvascular complications. Additionally, only 1.7 % of patients reported severe hyperglycemic complications such as DKA and HONC. This minimal complication rate could be related to the easy access to local health centers, enabling patients to seek prompt medical attention. As a result, individuals with significant hyperglycemia may present early, categorized as urgent cases, and receive appropriate management, preventing the progression to full-blown DKA or HONC. The reduced complication rate may indeed be associated with the accessibility of health services in primary care, effectively addressing these issues before they evolve into more severe conditions.

This study possesses several strengths. Notably, it is the first and

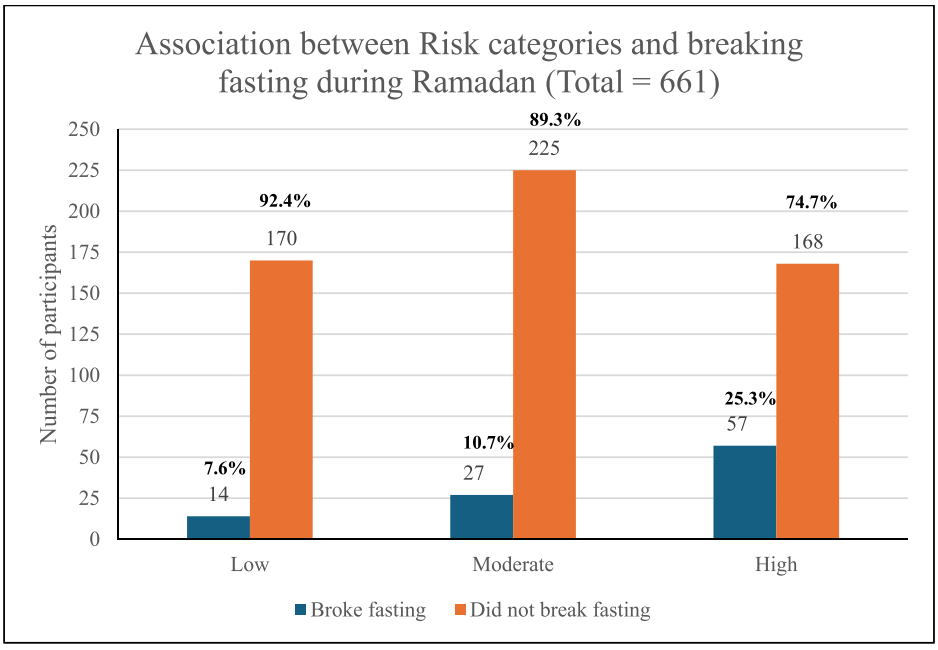

Fig. 3. Association between Risk categories and breaking fasting during Ramadan (Total = 661).

Table 4
Binary logistic regression of risk factors on breaking fasting during Ramadan.

Risk factors	OR (95 % CI)	P-value	Adjusted OR (95 % CI)	P-value
Diabetes type				
Type 1	2.487 (1.109, 5.575)	0.027**	1.643 (0.673, 4.009)	0.275
Type 2	Reference		Reference	
Duration of Diabetes				
≥10 years	1.576 (0.933, 2.661)	0.089	1.353 (0.765, 2.392)	0.298
<10 years	Reference		Reference	
Presence of hypoglycaemia				
Yes	1.776 (1.135, 2.778)	0.012**	1.077 (0.657, 1.766)	0.769
No	Reference		Reference	
Level of glycaemic control				
Uncontrolled	0.796 (0.509, 1.246)	0.318	0.723 (0.448, 1.167)	0.184
Controlled	Reference		Reference	
Type of treatment				
Insulin therapy	2.644 (0.921, 7.592)	0.071	2.416 (0.789, 7.398)	0.122
Hypoglycemia inducing oral therapy	0.917 (0.296, 2.844)	0.881	1.011 (0.314, 3.255)	0.985
Other therapy not including SU or Insulin	Reference		Reference	
Self-Monitoring of Blood Glucose (SMBG)				
Not conducted	1.034 (0.449, 2.382)	0.938	0.892 (0.363, 2.193)	0.804
Conducted	Reference		Reference	
Acute complications				
DKA/ HONC	2.191 (0.571, 8.406)	0.253	1.244 (0.299, 5.186)	0.764
No DKA or HONC	Reference		Reference	
MVD Complications/ Comorbidities				
MVD	1.666 (0.928, 2.989)	0.087	1.444 (0.779, 2.679)	0.244
No MVD	Reference		Reference	
Renal Complications/ Comorbidities				
eGFR ≤ 60 mL/min	1.773 (1.052, 2.989)	0.031**	1.786 (1.015, 3.142)	0.044**
eGFR > 60 mL/min	Reference		Reference	
Frailty and Cognitive function				
Yes	1.336 (0.374, 4.777)	0.656	0.993 (0.253, 3.904)	0.992
No	Reference		Reference	
Physical Labour				
Yes	1.569 (0.818, 3.012)	0.176	1.543 (0.771, 3.090)	0.221
No	Reference		Reference	
Previous Ramadan Experience				
Overall negative experience	4.118 (2.251, 7.535)	<0.001***	3.551 (1.866, 6.757)	<0.001***
No negative or positive experience	Reference		Reference	
Age				
≤70 years	0.776 (0.430, 1.397)	0.398	1.008 (0.518, 1.962)	0.981
>70 years	Reference		Reference	

**Significant at 0.05; ***Significant at 0.01.

Table 5
Association between Type of treatment and Breaking fast.

Type of treatment	Are there any days that you had to break your fast during Ramadan?	
	Yes	No
	n (%)	n (%)
Multiple daily mixed insulin Injections	30 (22.2)	105 (77.8)
Basal Bolus/Insulin pump	27 (26)	77 (74)
Once daily Mixed insulin	2 (16.7)	10 (83.3)
Basal Insulin	17 (12.7)	117 (87.3)
Glibenclamide	0 (0)	4 (100)
Gliclazide/MR or Glimepride or Repeglanide	18 (8)	207 (92)
Other therapy not including SU or Insulin	4 (8.5)	43 (91.5)

largest investigation conducted on diabetes patients in the Kingdom of Bahrain, evaluating the new IDF-DAR risk calculator. The sample size exceeded the necessary number for drawing conclusions, and the population was randomly selected, achieving a high response rate to the questionnaire. However, there are certain limitations to acknowledge. The study couldn't assess the impact of pregnancy on the risk due to patients being referred to secondary health care following the Ministry of Health protocol. Additionally, the fasting duration during Ramadan was fixed at 14 h, preventing an examination of longer fasting periods. Moreover, the phone interview method may introduce recall bias. It is important to note that the sample was selected from central diabetes clinics, focusing on uncontrolled complicated cases rather than controlled stable patients in other clinics. Consequently, this inclusion criterion resulted in a higher representation of patients at elevated risk.

6. Conclusion and recommendations

In conclusion, the data presented in this study seem to align with the risk calculator from the IDF, suggesting a degree of acceptance for its use in assessing the safety of fasting inpatients with diabetes. Nevertheless, it is prudent to reconsider the scoring system, giving more weight to certain risk factors, such as type of diabetes and negative experiences in previous Ramadans, compared to others like type of treatment and glycemic control, which seem to have a limited impact on the decision to break the fast. Considering the sensitivity of fasting during Ramadan as a spiritual undertaking, we propose conducting a systematic review that encompasses all relevant studies. This review should evaluate the IDF-DAR risk calculator and recommend practical modifications to enhance its accuracy in predicting risk, thereby minimizing unnecessary exemptions from fasting during Ramadan for diabetic patients.

7. Authors and Co-Authors

The study was conceived by Dr. Najla Shamsi, who also played a role in data collection and entry. Dr. Fadheela authored the introduction, Dr. Masooma contributed to the methodology, Dr. Jameel wrote the results, and Dr. Najla was responsible for the discussion and conclusion. All authors actively participated in data collection, analysis, and discussion. In the final stages, everyone collaborated in editing and revising the

manuscript. The order of contributions aligns with the extent of each author's involvement in the research.

CRediT authorship contribution statement

Najla Shamsi: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Methodology, Investigation, Data curation, Conceptualization. **Jameel Naser:** Writing – review & editing, Supervision, Investigation, Data curation. **Hanan Humaidan:** Writing – review & editing, Supervision, Data curation. **Abeer Al-Saweer:** Writing – review & editing, Software, Resources, Methodology, Data curation. **Masooma Jaafar:** Writing – review & editing, Writing – original draft, Software, Methodology, Investigation, Data curation. **Fadheela Abbas:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation. **Sumaya Al-Doseri:** Software, Data curation. **Najat Shabeeb:** Software, Methodology, Data curation. **Ebtihaj Al-Shaikh:** Data curation. **AbdulRasool Al-Dairi:** Data curation. **Khawla Mandoos:** Data curation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

The authors would like to express their sincere gratitude to their brilliant statistician Mr. Hasan Al-Basri for his work. Moreover, special thanks to the diabetic nurses who participated in data collection. The participating nurses are Mrs. Aziza Hasan, Mrs. Mariam Khalil, Mrs. Eman Ramadan, Mrs, Zahra Ateya, Mrs, Esmat Hasan, Mrs. Layla Ali, Mrs. Emama, Mrs. Hawra Yusuf, Mrs, Eman A.Nabi, Mrs, Khaireya, Mrs, Nadia and Mrs, Wadeea Hasan.

Appendix 1

TABLE 2 ELEMENTS FOR RISK CALCULATION AND SUGGESTED RISK SCORE FOR PEOPLE WITH DIABETES MELLITUS (DM) THAT SEEK TO FAST DURING RAMADAN

Risk Element	Risk Score
1. Diabetes type and duration	
Type 1 diabetes	1
Type 2 diabetes	0
2. Duration of Diabetes (years)	
A duration of ≥ 10	1
A duration of < 10	0
3. Presence of hypoglycaemia	
Hypoglycaemia unawareness	6.5
Recent Severe hypoglycaemia	5.5
Multiple weekly Hypoglycaemia	3.5
Hypoglycaemia less than 1 time per week	1
No hypoglycaemia	0
4. Level of glycaemic control	
HbA1c levels > 9% (11.7 mmol/L)	2
HbA1c levels 7.5–9% (9.4–11.7 mmol/L)	1
HbA1c levels < 7.5% (9.4 mmol/L)	0
5. Type of treatment	
Multiple daily mixed insulin injections	3
Basal Bolus/Insulin pump	2.5
Once daily Mixed insulin	2
Basal Insulin	1.5
Glibenclamide	1
Gliclazide/MR or Glimepride or Repeglanide	0.5
Other therapy not including SU or Insulin	0
6. Self-Monitoring of Blood Glucose (SMBG)	
Indicated but not conducted	2
Indicated but conducted sub-optimally	1
Conducted as indicated	0
7. Acute complications	
DKA/ HONC in the last 3 months	3
DKA/ HONC in the last 6 months	2
DKA/ HONC in the last 12 months	1
No DKA or HONC	0
8. MVD Complications/Comorbidities	
Unstable MVD	6.5
Stable MVD	2
No MVD	0
9. Renal Complications/Comorbidities	
eGFR < 30 mL/min	6.5
eGFR 30–45 mL/min	4
eGFR 45–60 mL/min	2
eGFR >60 mL/min	0
10. Pregnancy*	
Pregnant not within targets*	6.5
Pregnant within targets*	3.5
Not pregnant	0
11. Frailty and Cognitive function	
Impaired cognitive function or Frail	6.5
> 70 years old with no home support	3.5
No frailty or loss in cognitive function	0
12. Physical Labour	
Highly intense physical labour	4
Moderate intense Physical Labour	2
No physical labour	0
13. Previous Ramadan Experience	
Overall negative experience	1
No negative or positive experience	0
14. Fasting hours (location)	
≥ 16 hours	1
< 16 hours	0

DKA — Diabetic Ketoacidosis
HONC — Hyperglycaemic Hyperosmolar Nonketotic Coma
eGFR — Estimated glomerular filtration rate
CVD — Cardiovascular disease

*Pregnant and breastfeeding women have the right to not fast regardless of whether they have diabetes

FIGURE 1
Risk score and risk categories

Appendix 2

The phone questionnaire

1	Did you fast Ramadan?	Yes	No	
2	Are there any days that you had to break your fast during Ramadan?	Yes	No	
3	How many Days did you have to break your fast?			
4	What is/are the reasons for breaking your fast during Ramadan?	Hypoglycemia	Hyperglycemia	Other reasons
5	In case of breaking your fast due to hypoglycemia, did you confirm it by measuring your blood glucose at home?	Yes	No	
6	In case of breaking your fast due to hyperglycemia, did you confirm it by measuring your blood glucose at home?	Yes	No	

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