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Predictive Ability and the Clinical Validity of IDF-DAR Risk Score and Its Elements among Fasting People with Diabetes during Ramadan

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Abstract

Background and Aims This article aims to determine the predictive ability and the clinical validity of the IDF-DAR risk score and its elements among fasting people with diabetes during Ramadan.

Methods This prospective observational study was conducted from March to May 2022 at the Baqai Institute of Diabetology and Endocrinology, Karachi, Pakistan, with two participating centers from Peshawar (PAK) and Dubai (UAE). People with diabetes who intended to fast were recruited and categorized according to the IDF-DAR risk score. Fasting status and outcomes were assessed post-Ramadan.

Results A total of 953 fasting people with diabetes participated, of whom 542 (56.9%) were low, 254 (26.7%) moderate, and 157 (16%) high risk. Hypoglycemia occurred in 48 (30.1%) participants in the high-risk group compared with 33(6%) in the low-risk and 17 (6.6%) in the moderate-risk groups. Hyperglycemia was reported in 18 (3.3%) low-risk, 24 (9.4%) moderate-risk, and 24 (15.3%) high-risk participants. Hospitalization occurred in 3 (1.2%) participants in the moderate-risk group. Breaking of fast was most frequent among those with high-risk scores, affecting 20 (12.7%) participants. On multivariate analysis, type 1 diabetes (T1DM) and stage-3 chronic kidney disease (CKD) were the significant predictors of adverse events during fasting, with adjusted odds ratios of 8.33 (95% CI: 4.5–15.45; $p < 0.0001$) and 3.01 (95% CI: 1.08–8.39; $p = 0.035$), respectively.

Conclusion Our study supports the predictive ability and clinical validity of the IDF–DAR risk score. High-risk scores acquired by nonmodifiable factors, such as T1DM and stage-3 CKD, require careful consideration, while optimizing modifiable factors can lower the score and enable safer fasting.

Keywords
- Ramadan fasting
- IDF-DAR risk score
- acute complications
- chronic kidney disease
- type 1 diabetes

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Introduction

Fasting during Ramadan is observed by millions of Muslims worldwide and involves complete abstinence from food, drink, and oral medications during daylight hours.[1] While fasting is recommended for healthy individuals, exemptions are granted to children, the frail elderly, pregnant or nursing women, those menstruating, and people with acute or chronic health conditions.[2]

Changes in eating habits, physical activity, and sleep patterns during Ramadan can disrupt metabolic homeostasis, particularly in individuals with chronic conditions such as uncontrolled diabetes, hypertension, or chronic kidney disease (CKD). These disruptions may increase the risk of hypoglycemia, hyperglycemia, dehydration, and diabetic ketoacidosis (DKA). Despite these risks, many Muslims living with diabetes do not perceive themselves as ill or exempt and choose to fast.[3,4] This can be challenging for both people with diabetes and their health care professionals (HCPs), highlighting the need for evidence-based recommendations to support safe fasting practices.

Earlier recommendations, such as the 2016 Diabetes and Ramadan (DAR) practical guidelines, introduced a categorical risk stratification model classifying individuals into very-high, high, and low-to-moderate risk categories.[5] However, subsequent evidence indicated that many individuals classified as high-risk were still able to complete fasting safely, suggesting that this model may have been overly restrictive.[6] To address these limitations, the International Diabetes Federation–Diabetes and Ramadan (IDF–DAR) 2021 guidelines introduced a more refined risk-scoring system. This tool incorporates multiple clinical and lifestyle parameters to guide risk assessment and facilitate shared decision-making between patients and HCPs.[7] However, the scoring system remains largely based on expert consensus, and its clinical validity and predictive accuracy are not known.

Therefore, recent studies have begun to evaluate the IDF-DAR tool's performance in real-world settings, consistently showing that higher scores are associated with lower fasting adherence and greater risk of complications, supporting its predictive validity.[8] Despite initial validations, uncertainties remain regarding its performance across different populations, highlighting the need for further evaluation.[9]

Therefore, the present study not only assesses the overall clinical validity of the IDF–DAR risk score in fasting individuals with diabetes but also examines the predictive value of its individual elements, providing a more detailed understanding of its applicability in predicting fasting adherence and acute complications.

Methodology

This prospective observational study was conducted between March and May 2022 at the outpatient departments of the Baqai Institute of Diabetology and Endocrinology (BIDE), Karachi, Pakistan, in collaboration with two additional centers: AIMS Sugar Hospital, Peshawar, Pakistan, and Pakistan Medical Center, Dubai (UAE). The study adhered to the ethical principles outlined in the Declaration of Helsinki (revised 2013). Ethical approval was obtained from the Institutional Review Board (IRB) of BIDE (IRB-BIDE/MYAH-MEDANI/-07–20–21–009). For the collaborating centers, a formal permission/waiver was obtained, considering BIDE's IRB approval.

Before onset, a standardized study protocol was developed and disseminated to all three centers to maintain consistency and minimize inter-center variability. All data collectors and healthcare staff received joint online training sessions to ensure consistent use of the IDF-DAR 2021 risk classification, uniform delivery of Ramadan-focused diabetes education following IDF-DAR guidelines, and standardized administration of the questionnaire and documentation of complications.

A central monitoring team at BIDE supervised procedural adherence through weekly virtual meetings, record reviews, and random cross-checking. All three centers used the same structured tools, instructions, definitions, and follow-up procedures.

People with diabetes aged 25 to 80 years were asked during the pre-Ramadan screening visit whether they intended to fast. Eligible individuals who confirmed their intention were invited to participate, and the study objectives, procedures, risks, and benefits were explained. Written informed consent was obtained from those who agreed to participate at each of the participating centers. The IDF-DAR 2021 risk score chart was used without any modification to categorize fasting risk. All participants received individualized Ramadan-specific diabetes education, including dose adjustments, recognition of hypo- and hyperglycemia symptoms, and necessary precautions in case of acute complications. Patients identified as high-risk were specifically counseled about their elevated risk of developing complications during fasting, and only those who still chose to fast after counseling were included in the study.

A dedicated emergency contact number was provided to all participants to report any acute event during fasting. In addition, all participants, particularly those categorized as high-risk, received weekly follow-up messages and phone calls throughout Ramadan to reinforce education, assess glycemic status, and ensure timely reporting of symptoms. Those unwilling or medically advised not to fast, those not intending to participate in the study; patients with a recent history of severe hypoglycemia events (requiring assistance, seizure, or loss of consciousness); any current acute illness or hospitalization; and critically ill or clinically unstable patients were excluded.

During the pre-Ramadan visit (i.e., 4–6 weeks before Ramadan), a total of 1,053 individuals were screened for eligibility. Of these, 1,027 participants were initially recruited, while 26 were excluded because they met one or more exclusion criteria, declined to fast, refused participation, or were advised against fasting by their physicians. Data were collected using a two-section, closed-ended questionnaire: Section A was used to collect patients' demographic profile, anthropometric measurements, and fasting risk stratification using the IDF-DAR risk score. The primary

outcomes of the study were major hypoglycemia and major hyperglycemia during fasting. Secondary outcomes included hospitalizations, emergency visits, or events requiring discontinuation of fasting. Participants were instructed to maintain their personal diary documenting the frequency of any of these complications that occurred during fasting. These entries were cross-verified during the post-Ramadan follow-up visit (within 4 weeks after Ramadan) along with the fasting status, using Section B of the questionnaire.

Data analysis was performed using the Statistical Package for Social Sciences (SPSS) version 20. Continuous variables were recorded as mean ± standard deviation, and categorical variables as frequency (percentages). The chi-square test or Fisher's exact test was used to compare groups. Stepwise regression was used to identify the factors that have significantly contributed to getting moderate- to high-risk scores. A *p*-value less than 0.05 was considered statistically significant.

Operational Definitions

Minor hypoglycemia: blood sugar level equal to or less than 70 mg/dL by capillary glucometer (irrespective of symptoms).

Minor hyperglycemia: blood sugar level equal to or greater than 200 mg/dL by capillary glucometer.

Major hypoglycemia: blood sugar level equal to or less than 40 mg/dL by capillary glucometer (irrespective of symptoms) or hypoglycemia that required third-person assistance, irrespective of blood sugar level.

Major hyperglycemia: RBS > 300, diabetic ketoacidosis, hyperosmolar hyperglycemic state.

Results

Among the 1,027 recruited participants, 42 did not fast during Ramadan and were therefore excluded from post-Ramadan assessment. An additional 32 individuals were excluded due to incomplete follow-up, missing post-Ramadan visits, or inadequate documentation of Ramadan-related data. Consequently, 953 participants who fasted during Ramadan and had complete datasets were included in the final analysis. The process of participant recruitment, exclusions, and inclusion in the final analysis is summarized in the participant flow diagram (►**Fig. 1**).

The mean age of the participants was 49.24 ± 13.1 years, with an approximately equal gender distribution. Of these, 859 (90.1%) had type 2 diabetes (T2DM), and 94 (9.9%) had type 1 diabetes (T1DM). According to the IDF-DAR scoring system, 542 (56.9%) people were classified as low-risk, 254 (26.7%) as moderate-risk, and 157 (16%) as high-risk of fasting at enrollment. Baseline characteristics of the study population are summarized in ►**Table 1**.

Among them, 478 (88.2%) in the low-risk group, 224 (88.2%) in the moderate-risk group, and 118 (75.2%) in the high-risk group completed fasting for the full month of Ramadan ($p < 0.0001$). Rates of complications varied significantly by risk category. In the high-risk group, minor and major hypoglycemia occurred in 30 (19.1%) and 18 (11.4%) participants, respectively ($p < 0.0001$), while 20 (12.7%) reported breaking of fast mainly due to hypoglycemic events ($p < 0.0001$). In the moderate-risk group, minor and major hyperglycemia were recorded in 10 (3.9%) and 14 (5.9%)

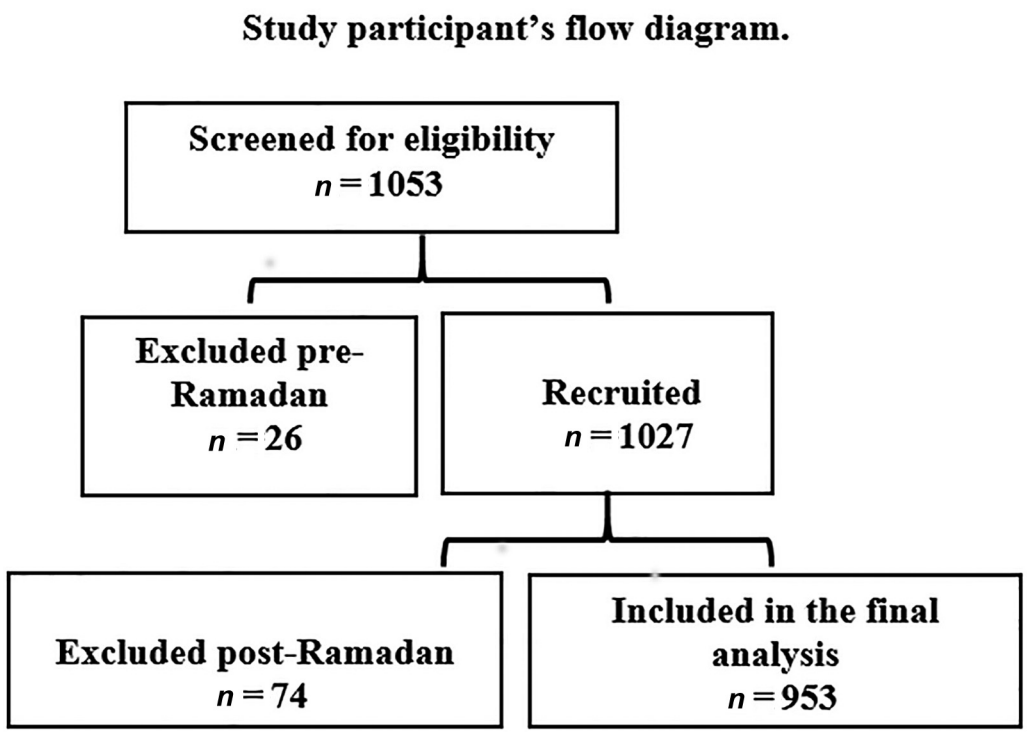

Fig. 1 Study participants' flow diagram.

Table 1 Demographic characteristics of the study population

Parameters	*n* (%) or mean ± SD
n	953
Gender	
Male	461 (48.4)
Female	492 (51.6)
Age (years)	49.24 ± 13.1
BMI (kg/m^2)	28.97 ± 5.64
Blood pressure	
SBP (mm Hg)	124.93 ± 17.32
DBP (mm Hg)	78.27 ± 10.15
Diabetes type	
II	859 (90.1)
I	94 (9.9)
Duration of diabetes (years)	
< 10	644 (67.6)
≥10	309 (32.4)
History of hypoglycemia	
< 1/week	102 (10.7)
1–6/week	32 (3.4)
Daily mild	4 (0.4)
Recurrent/severe	8 (0.8)
Hypoglycemia unawareness	9 (0.9)
Characteristics of glycemic control (HbA1c %)	
< 7.5	339 (35.6)
7.5–9	275 (28.8)
> 9	339 (35.6)
SMBG	
Conducted as indicated	554 (58.1)
Indicated but conducted suboptimally	248 (26)
Indicated but not conducted	151 (15.8)
History of acute complications	
DKA/HONC in the last 12 mo	4 (0.4)
DKA/HONC in the last 6 mo	2 (0.2)
DKA/HONC in the last 3 mo	4 (0.4)
Chronic complications/comorbidities	
Normal eGFR	905 (95)
45–60 mL/min	30 (3.1)
30–45 mL/min	13 (1.4)
< 30 mL/min	5 (0.5)
Pregnancy	
Pregnant within the target	4 (0.4)
Pregnant not within the target	1 (0.1)
Frailty and cognitive function	
Frail	2 (0.2)
Physical labor	
No	858 (90)
Intensive	95 (10)
Previous Ramadan experience	
No negative or positive experience	884 (92.8)
Overall negative experience	69 (7.2)
Fasting hours (location)	
< 16 h	917 (96.2)
> 16 h	36 (3.8)
Diabetes treatment	
Multiple daily mixed insulin injections	180 (18.8)
Basal bolus/insulin pump	3 (0.3)
Once daily mixed insulin	6 (0.6)
Basal insulin	127 (13.3)
Glibenclamide	13 (1.36)
Gliclazide MR or glimepiride or repaglinide	356 (37.2)
Other therapy not including SU or insulin	292 (30.6)
IDF-DAR risk score	
Low	542 (56.9)
Moderate	254 (26.7)
High	157 (16)

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; DKA/HONC, diabetic ketoacidosis/hyperosmolar nonketotic coma; eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin; IDF-DAR, International Diabetes Federation Diabetes and Ramadan; SBP, systolic blood pressure; SMBG, self-monitoring of blood glucose.
Note: Data presented as *n* (%) or mean ± SD.

participants, respectively ($p = 0.02$), and hospitalization occurred in 3 (1.2%) cases (►**Table 2**).

We conducted an element-level analysis to identify which specific element contributed most strongly to adverse events during fasting. For this analysis, "adverse events" were defined as the occurrence of any one of the previously described complications (minor/major hypoglycemia, hyperglycemia, breaking of the fast, or hospitalization). These adverse events were more frequent among individuals with T1DM: 39 (48.8%), $p < 0.0001$; those with a diabetes duration ≥10 years: 38 (47.5%), ($p = 0.003$); a history of hypoglycemia (<1 weekly): 22 (27.5%), ($p < 0.0001$); poor glycemic control: 38 (47.5%), ($p = 0.004$); or reduced estimated glomerular filtration rate (eGFR) between 30 and

Table 2 Fasting status and frequency of complications among participants during Ramadan belonging to different IDF-DAR risk scores

Parameters	Low	Moderate	High	*p*-Value
***n* (%)**	**542 (57)**	**254 (27)**	**157 (16)**	**–**
Days fasted				
1–10	17 (3.1)	9 (3.5)	7 (4.4)	<0.0001
11–20	47 (8.7)	21 (8.3)	32 (20.4)	
21–30	478 (88.2)	224 (88.2)	118 (75.2)	
Hypoglycemia	33 (6)	17 (6.6)	48 (30.1)	<0.0001
Minor	29 (5.3)	15 (5.9)	30 (19.1)	
Major	4 (0.7)	2 (0.8)	18 (11.4)	
Hyperglycemia	18 (3.3)	24 (9.4)	24 (15.3)	0.025
Minor	12 (2.2)	10 (3.9)	6 (3.8)	
Major	6 (1.1)	14 (5.9)	18 (11.4)	
DKA/HHS				
DKA	0 (0)	0 (0)	1 (0.7)	N/A
HHS	3 (0.5)	2 (0.8)	0 (0)	
Hospitalization	0 (0)	3 (1.2)	1 (0.6)	N/A
Reason for hospitalization				
Major hypoglycemia	–	0 (0)	1 (100)	N/A
Major hyperglycemia	–	2 (66.6)	0 (0)	
Other medical reasons	–	1 (33.3)	0 (0)	
Breaking of fast?	8 (1.4)	11 (4.3)	20 (12.7)	<0.0001
Reason for breaking the fast?				
Minor hypoglycemia	1 (14.3)	5 (45.5)	7 (35)	N/A
Major hypoglycemia	3 (42.8)	1 (9.1)	12 (60)	
Minor hyperglycemia	1 (14.2)	0 (0)	0 (0)	
Major hyperglycemia	1 (14.2)	1 (9.1)	1 (5)	
Other medical reasons	2 (28.6)	4 (36.4%)	0 (0)	

Abbreviations: DKA/HHS, diabetic ketoacidosis/hyperosmolar hyperglycemic state; N/A, not applicable.
Note: Data presented as *n* (%); *p*-value < 0.05 considered to be statistically significant.

60 mL/min/1.73 m^2 ($p = 0.003$). Treatment with once-daily mixed insulin 2 (2.5%; $p = 0.02$) and multiple daily mixed insulin regimens 44 (55%; $p < 0.001$) was also significantly associated with adverse outcomes (►**Table 3**).

Multivariate regression showed that the odds of developing acute complications were significantly higher among people with T1DM (AOR: 8.33, 95% CI: 4.5–15.45; $p < 0.0001$) and stage-3 CKD (AOR: 3.01, 95% CI: 1.08–8.39; $p = 0.035$; ►**Table 4**).

Discussion

In this study, we evaluated the predictive ability and clinical validity of the IDF–DAR risk stratification tool, along with its individual elements, among fasting people with diabetes during Ramadan. Our findings demonstrate that individuals with higher risk scores were more likely to develop fasting-related complications compared with those with lower scores. Importantly, T1DM and stage-3 CKD emerged as the strongest predictors of adverse outcomes, underscoring the clinical relevance of the risk score, whereas most other elements showed limited predictive value.

At baseline, fewer than half of our cohort was classified as moderate- or high-risk; however, a considerable proportion of these individuals still fasted for the entire Ramadan month, i.e., 224 (88.2%) and 118 (75.2%), respectively. This pattern aligns closely with previous reports from Bahrain (85%), Bangladesh (72.8%, 49.3%), Saudi Arabia (70.4%, 53.2), and the UAE (84.7%, 80.2%), where moderate- or high risk-groups, including those with poorly controlled T2DM and T1DM, or advanced comorbidities, observed the full month of fasting despite medical advice.[8,10–12] This consistent trend indicates that although the IDF–DAR tool effectively identifies individuals at higher risk, fasting decisions are often shaped by personal choices, social influences, and faith-

Table 3 Association of IDF-DAR risk elements with complications that occurred

Parameters	Complications			*p*-Value
	No	Yes		
n (%)	873 (91.6)	80 (8.4)		
Gender				
Male	421 (48.2)	40 (50)		0.761
Female	452 (51.8)	40 (50)		
Diabetes type				
II	818 (93.7)	41 (51.2)		<0.0001
1	55 (6.3)	39 (48.8)		
Duration of diabetes (years)				
<10	602 (69)	42 (52.5)		0.003
≥10	271 (31)	38 (47.5)		
History of hypoglycemia				
No hypoglycemia	757 (86.7)	41 (51.2)		<0.0001
<1 time per week	80 (9.2)	22 (27.5)		
1–6 times per week	22 (2.5)	10 (12.5)		
Daily mild hypo	2 (0.2)	2 (2.5)		
Recurrent/severe hypo	6 (0.7)	2 (2.5)		
Hypo unawareness	6 (0.7)	3 (3.8)		
Characteristics of glycemic control (HbA1c %)				
<7.5	324 (37.1)	15 (18.8)		0.004
7.5–9	248 (28.4)	27 (33.8)		
>9	301 (34.5)	38 (47.5)		
SMBG				
Conducted as indicated	504 (57.7)	50 (62.5)		0.159
Indicated but conducted suboptimally	234 (26.8)	14 (17.5)		
Indicated but not conducted	135 (15.5)	16 (20)		
Acute complications				
No	865 (99.1)	78 (97.5)		N/A
In the last 12 mo	4 (0.5)	0 (0)		
In the last 6 mo	2 (0.2)	0 (0)		
In the last 3 mo	2 (0.2)	2 (2.5)		
Chronic complications/ comorbidities normal eGFR	836 (95.8)	69 (86.2)		0.003
45–60 mL/min	23 (2.6)	7 (8.8)		
30–45 mL/min	10 (1.1)	3 (3.8)		
<30 mL/min	4 (0.5)	1 (1.2)		
Pregnancy				
Not pregnant	869 (99.5)	79 (98.8)		N/A
Pregnant within the target	4 (0.5)	0 (0)		
Pregnant not within the target	0 (0)	1 (1.2)		
Frailty and cognitive function				
No frailty	871 (99.8)	80 (100)		N/A
Frail	2 (0.2)	0 (0)		

Table 3 (*Continued*)

Parameters	Complications			*p*-Value
	No	Yes		
Physical labor				
No	788 (90.3)	70 (87.5)		0.438
Intensive	85 (9.7)	10 (12.5)		
Previous Ramadan experience				
No negative or positive experience	813 (93.1)	71 (88.8)		0.148
Overall negative experience	60 (6.9)	9 (11.2)		
Fasting hours (location)				
<16	837 (95.9)	80 (100)		N/A
≥ 16	36 (4.1)	0 (0%)		
Diabetes treatment				
Other therapy not including SU or insulin				
No	591 (67.7)	70 (87.5)		<0.0001
Yes	282 (32.3)	10 (12.5)		
Once daily mixed insulin				
No	869 (99.5)	78 (97.5)		0.027
Yes	4 (0.5)	2 (2.5)		
Multiple daily mixed insulin injections				
No	737 (84.4)	36 (45)		<0.0001
Yes	136 (15.6)	44 (55)		
Gliclazide MR or glimepiride or repaglinide				
No	551 (63.1)	68 (85)		<0.0001
Yes	343 (39.3)	12 (15)		
Glibenclamide				
No	860 (98.5)	80 (100)		N/A
Yes	13 (1.5)	0 (0)		
Insulin pump				
No	870 (99.7)	80 (100)		N/A
Yes	3 (0.3)	0 (0)		
Basal insulin				
No	755 (86.5)	68 (85)		0.84
Yes	118 (13.5)	12 (15)		

Abbreviations: eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin; N/A, not applicable; SMBG, self-monitoring of blood glucose.
Note: Data presented as *n* (%) or mean $\pm$ SD. *p*-Value <0.05 is considered to be statistically significant.

Table 4 Validation of IDF-DAR risk elements in people with moderate- to high-risk scores

Factors		AOR (95% CI)	*p*-Value
Type of diabetes	Type 2	1	<0.0001
	Type 1	8.33 (4.5–15.45)	
Chronic complications/comorbidities	normal eGFR	1	
	45–60 mL/min	3.01 (1.08–8.39)	0.035
	30–45 mL/min	2.4 (0.54–10.64)	0.251
	<30 mL/min	9.5 (0.78–16.04)	0.078

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; eGFR, estimated glomerular filtration rate.
Note: Stepwise Backward-Wald regression was used; variables included in the model: demographic characteristics and all the IDF-DAR risk score elements; *p*-value < 0.05 considered to be statistically significant.

related commitments that extend beyond clinical evaluation.[13]

In our cohort, major hypoglycemia occurred in 11.4% of high-risk individuals, almost 15-fold higher than in the moderate-risk (0.8%) and low-risk groups (0.7%). This trend of increasing hypoglycemia with higher risk scores is consistent with previous studies. Alfadhli et al reported 28.3% in the high-risk group, around threefold higher than in moderate- and low-risk groups.[11] Similarly, Mohammed et al, Al-Malki et al, and Mazloum et al showed the highest hypoglycemia rates among high-risk participants (10.5, 48.7, and 45.3%, respectively).[14–16] Kamrul-Hasan et al observed a relatively lower rate (7.5%), roughly 3.7-fold higher than the lower-risk groups.[10] A few studies, such as Baynouna et al, reported exceptions (moderate-risk: 15.8% vs. high-risk 12.7%), attributed to more conservative medication adjustments, closer monitoring, and selective fasting among high-risk individuals.[12]

Major hyperglycemia in our study was also 4.5-fold higher in high-risk participants (11.4%) compared with 5.9 and 1.1% in moderate- and low-risk groups, respectively. Similar fold increases (3.5–3.86) in the high-risk groups were observed by Kamrul-Hasan and Alfadhli et al (4.5–8.3%),[10,11] whereas Mohammed et al reported higher absolute rates (23.8%) with comparable fold increases (threefold).[14] Although Farooq et al found that fasting participants had higher hypoglycemia (58.3 vs. 29.3%) but lower hyperglycemia (27.8 vs. 55.2%) than nonfasters,[17] risk stratification was not reported, limiting direct comparison.

Hospital admissions and acute metabolic complications observed were infrequent and mostly nonsignificant. Admissions occurred mainly in the moderate-risk group, 3 (1.2%), due to major hyperglycemia, 2 (66.6%). These rates were slightly higher than the single admission reported by Mohammed et al,[14] but lower than that reported by Alfadhli et al, 10 (3.8%), and Baynouna et al, 9 (12%), which were predominantly observed in high-risk groups.[11,12] DKA and hyperosmolar hyperglycemic state (HHS) were similarly rare in this cohort, with DKA in one participant (0.7%) in the high-risk group and HHS in two participants (0.8%) in the moderate-risk group, consistent with that of Alfadhli et al (DKA: 0.4%) and Al-Malki (one high-risk T1DM patient hospitalized for DKA).[10,15] Finally, the rate of breaking of fast was also higher in our high-risk participants (12.7%), mainly due to major hypoglycemia, compared with 4.3% due to moderate-risk, and 1.4% due to low-risk. These frequencies are lower than reported by Shamsi et al (25.3%) in high-risk participants, similarly due to hypoglycemia[8] and Alfadhli (61.5% of T1DM and 12.7% of T2DM).[10]

Overall, despite numerical differences, most studies agree on the central message that individuals with higher IDF–DAR risk scores experience more hypo- and hyperglycemia and related adverse events during Ramadan, supporting the clinical value of the risk score. Yet, complications are not universal: in our cohort, only 8.4% were affected, while 91.6% fasted safely despite many being classified as high risk. This shows that not everyone categorized as high-risk is at the same level of risk, as patients reach this classification for different reasons. Consequently, identifying which specific risk elements truly contribute to fasting-related adverse outcomes becomes crucial.

Therefore, our study further examined the contribution of individual IDF–DAR risk elements, and we found that T1DM, longer disease duration, poor glycemic control, impaired kidney function, complex insulin use, and a history of hypoglycemia were initially associated with complications, echoing earlier findings.[8] Interestingly, some factors showed paradoxical associations, where both regular and irregular glucose monitoring, as well as both use and non-use of sulfonylureas or other oral agents, appeared to predict complications. These patterns most likely reflect confounding by indication, surveillance bias from increased event detection, heterogeneity in therapy use, and small subgroup effects, rather than true bidirectional causal relationships.

After adjustment, only T1DM and stage-3 CKD remained significant predictors. The elevated risk in T1DM has been consistently demonstrated in the available Ramadan studies,[18] while the link with stage-3 CKD aligns with emerging evidence from multi-country and kidney-focused cohorts showing higher rates of both glycemic and nonglycemic complications in these patients.[19,20] This may be due to altered drug handling, fluid balance issues, and reduced physiological reserves in these patients.

Taken together, our study reaffirms the clinical validity of the IDF–DAR risk score while illustrating that not all components are equally predictive of actual risk. These differences have important clinical implications. In real-world Ramadan care, many individuals categorized as “high-risk” based on their total score can still fast safely, as reflected in our study. This means clinicians should look beyond the total score and focus on the specific elements that contribute to a higher score for each patient.

People with nonmodifiable elements such as T1DM and advanced CKD need more intensive pre-Ramadan counseling, closer monitoring, and, in some cases, clear advice against fasting. At the same time, their overall risk can often be reduced before Ramadan by optimizing modifiable factors such as glycemic control, medication regimens, and prior hypoglycemia history, which in turn enhances safety and allows more individuals to fast with a lower risk of adverse events under proper medical supervision.[21]

These observations are likely relevant beyond Pakistan, as similar patterns have been described across different Muslim populations and healthcare systems.[9,15,22] Risk stratification also offers cost-effectiveness advantages, especially in low-resource settings, by helping clinicians focus limited time, education, and monitoring efforts on the smaller group at greatest risk.

Finally, our findings highlight clear directions for future research. More prospective studies are needed to determine which specific risk-score elements have the strongest predictive value across different regions and healthcare contexts, enabling refinement of the existing framework. Trials that test more personalized pre-Ramadan interventions, particularly for people with T1DM or CKD, could help determine which strategies truly reduce risk. Evaluating the

economic impact of risk-based care pathways will also be important for creating Ramadan programs that are both effective and scalable.

Our study has several strengths. The prospective, multicenter design across three centers allowed real-time assessment of fasting-related adverse events, which were systematically documented, minimizing the risk of bias and enhancing the robustness of findings. With 953 participants, we evaluated overall risk patterns as well as individual IDF–DAR risk elements, providing practical insights for personalized pre-Ramadan care. Consistent patterns across centers suggest applicability to diverse Muslim populations and healthcare settings. However, there are limitations. Despite being multicenter, only three centers were included, which may limit broader generalizability. Some high-risk subgroups, such as stage 3 CKD or T1DM patients, were small, resulting in wide confidence intervals. The observational design cannot fully exclude residual confounding, particularly for paradoxical associations like glucose monitoring or oral agent use. Additionally, very frail patients, those with cognitive impairment, and pregnant women were underrepresented, limiting applicability to these groups

Conclusion

Our study supports the predictive ability and clinical validity of the IDF–DAR risk score for identifying individuals at higher risk of fasting-related complications during Ramadan. High-risk scores acquired by nonmodifiable factors, such as T1DM and stage-3 CKD, need careful pre-Ramadan assessment, intensive counseling, close monitoring, and, in some cases, advice against fasting. However, modifiable factors can be optimized in advance to lower the score and allow many patients to fast safely under medical supervision.

Declaration of Financial/Other Relationships
The authors report no financial or personal relationships that could have affected the conduct or outcomes of this research.

Details of the Earlier Presentation
Preliminary data of this study were presented at the International Diabetes Federation Congress 2022 (December 4–7, Lisbon, Portugal).

Authors' Contributions
S.Y.: Concept and design, data collection, data interpretation, and writing the manuscript.

M.Y.A.: Concept and design, interpretation of data, editing, and reviewing the manuscript.

S.Z.: Responsible for data collection and management in her respective areas, reviewed and approved the final manuscript.

Ethical Approval Statement
The study adhered to the ethical principles outlined in the Declaration of Helsinki (revised 2013). Ethical approval was taken from the Institutional Review Board (IRB) of BIDE (IRB-BIDE/MYAHMEDANI/-07–21–20–009). For the collaborating centers, a formal permission/waiver was obtained, considering BIDE's IRB approval.

Conflict of Interest
The authors declare that there are no conflicts of interest regarding the publication of this paper.

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