

Ramadan Risk Stratification by International Diabetes Federation and Diabetes & Ramadan International Alliance (IDF-DAR) Risk Calculator in Bangladeshi People with Diabetes Mellitus who wished to Fast in 2022

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Introduction:

Fasting during the daylight hours of Ramadan is an obligatory prayer for all eligible Muslims. However, many Muslims observe fasting despite their exemption due to various physiological as well as advanced disease conditions.¹ Due to complete refrain from both foods and drinks, people with diabetes mellitus (DM) are at increased risk of glycemic variability as well as dehydration. There are increased risks of hypoglycemia, diabetic

Abstract:

Background:

Risk stratification is an essential and first component of the pre-Ramadan assessment of patients with diabetes mellitus (DM) who wish to fast. Limited data are reported from Bangladesh regarding risk stratification of people with DM who wish to fast.

Objective:

To determine the risk status of people with DM who wish to fast during Ramadan.

Methods:

This cross-sectional observational study was done among Muslim people of DM with at least one year of experience of Ramadan in previous years after their diagnosis. Along with baseline characteristics, the individual 14 risk elements of the International Diabetes Federation and Diabetes & Ramadan International Alliance (IDF-DAR) risk calculator-2021 were assessed. Patients were categorized into low, moderate, and high risk with a total score of 0-3, 3.5-6, and ≥ 6.5 respectively. Moderate and high-risk patients were counseled about their risk of fasting and requested to reconsider their wishes.

Results:

Among 569 participants, (mean age 50.97 ± 12.02 years, male-female ratio 36.2:63.8) 37.8%, 38.8%, and 23.4% had high, moderate, and low risk respectively. Risk scores were significantly higher in older age ($p < 0.001$), male sex ($p = 0.024$), residence in Chattogram than Rajshahi division ($p = 0.009$) as well as housewife and businessman than other occupations ($p = 0.012$). Despite knowing the risks of fasting, 88.8% of people with high risk and 96.8% of people with moderate risks still wished to fast. The people who still wished to fast despite knowing their risks of fasting had significantly lower percent of macrovascular disease ($p = 0.039$), lower creatinine levels ($p < 0.001$), with a lower percent of dipstick proteinuria ($p = 0.010$), and use of insulin ($p = 0.021$) than those who changed their decision.

Conclusions:

Nearly 90% of persons with DM with moderate/high risk for fasting still wished to fast despite their exemption. These at-risk population needs guidance, monitoring, and follow-up for safe fasting.

Keywords: Ramadan, Fasting, Diabetes Mellitus, IDF-DAR risk stratification, Bangladesh

ketoacidosis, hyperglycemic hyperosmolar state, and thrombosis.² With increasing DM duration and the development of complications, the risks of fasting are increased and may be life-threatening. People with type 1 DM (T1DM) are especially vulnerable to acute complications due to absolute insulin deficiency.³ Besides, patients' physical activity, duration of fasting, and type of medications may be relevant. So, individualized management is required according to evidence-based

medicine for safe fasting. Due to a lack of adequate evidence, it is usually based on expert opinion. However, International Diabetes Federation along with Diabetes & Ramadan International Alliance (IDF-DAR) has recently published guidelines 2016 for the management of people with DM for safe fasting. The first step for a person who wishes to fast is to stratify the risks of fasting. In the recent 2021 guideline by IDF-DAR, a risk scoring calculator with 14 risk elements has been suggested. People in the moderate-severe risk category are not allowed to fast.²

Diabetes mellitus is a growing pandemic with increasing prevalence and health care burden. About 1/4th of the world population are Muslims and the global prevalence of Muslims is increasing. With the increasing prevalence of DM, the Muslim majority countries will be affected more.⁴ Around 31% of Muslims live in South Asia. A survey conducted in three countries of South Asia including Bangladesh showed that there were many myths among people with DM regarding fasting during Ramadan.⁵ Bangladesh is 4th in the ranking of Muslim-populated countries (15.37 million, 90.8% of the total population) in the world.⁶ More than two-thirds of Bangladeshi patients with DM fast for at least 15 days are found in an outpatient setting.⁷ Previous studies from Bangladesh supported the safety of fasting in type 2 DM (T2DM), T1DM, and even in pregnant women.⁸⁻¹⁰ While fasting was found to deteriorate metabolic status, pre-Ramadan education, counseling, and drug adjustment to people with DM not only ensured safe fasting but also improved metabolic profile in Bangladeshi people with DM.¹¹⁻¹³ However, only one-third of patients with DM visited for pre-Ramadan counseling with suboptimal practice and complications.⁶ Pre-Ramadan risk assessment facilitates individualized management. There are lack of data about the risk stratification of patients with DM who wish to fast. The aim of this study was to see the risk status according to IDF-DAR, 2021 guidelines and the percentage of patients with DM who wish to fast despite their risk of fasting during Ramadan.

Methods:

This cross-sectional observational study was done three months prior to the onset of Ramadan, 2022 at 14 sites in Bangladesh (five medical college hospitals, one Zilla hospital, and nine private chambers) among Muslim people of DM with at

least one year of experience of Ramadan in previous years after their diagnosis who wished to fast during Ramadan, 2022. The study was conducted by maintaining the ethical issues as per the declaration of Helsinki. Informed written consent was taken from each participant. Eligible participants were directly interviewed by the investigators to collect data regarding baseline characteristics, complications, co-morbidities, and current drug history. Patients were asked and investigation findings were checked to fill up the 14 risk elements of IDF-DAR risk stratification. After adding all the scores, the patient's risk category was determined. Patients were divided into low (0-3), moderate (3.5-6), and high (≥ 6.5) risk category as per the guideline.² The patients with moderate and high-risk groups were informed about their risks of fasting and then asked whether they still wished to fast and noted as yes or no. Data were entered and analyzed by SPSS software version 28.0. Numerical data were checked for distribution. Normally distributed data (age) were expressed in mean \pm standard deviation (SD) and skewed data (alanine aminotransferase, ALT; creatinine, HbA1C, total risk score) were expressed in median (inter-quartile range, IQR). Qualitative data were expressed in frequency (percentage). In case of missing data, the available number was mentioned within the third bracket. Association between/among groups was analyzed by independent-sample T-test, Mann-Whitney U test, Kruskal-Wallis one-way ANOVA with pairwise comparison by Dunn's test or Pearson's chi-square test with post hoc analysis from adjusted standardized residuals as appropriate. A two-tailed p-value below 0.05 was considered statistically significant.

Results:

The 14 risk elements and their risk scores with frequency (%) among the study population are shown in Table-I. Only four patients had T1DM. Among them, only one had no history of hypoglycemia and conducted self-monitoring of blood glucose (SMBG) regularly. All had HbA1C above 7.5% and two had acute complications in the last year. Around one-third of the total study, the population had DM for at least 10 years. Around 15% had hypoglycemia of different frequencies. Nearly 40% had very poor glycemic status ($>9\%$). Premix insulin was the most common insulin regimen. Around 31% took safer sulfonyl-

lureas. Nineteen percentage of the study population took antidiabetics other than insulin or sulfonylureas. Most of the participants did not conduct SMBG as indicated. Only 3% had a history of acute complications. Only 2% had unstable macrovascular disease and 20% had diabetic kidney disease (DKD) with an estimated glomerular filtration rate (eGFR) ≤ 60

ml/min/1.73 m² body surface area. Among four pregnant patients, three had uncontrolled DM. Most of the patients had no frailty or cognitive impairment. Most of the participants were physically inactive. Around 9% had an overall negative experience in the previous Ramadan. The duration of fasting in our country was less than 16 hours in 2022.

Table-I: Elements for risk calculation and suggested risk score for people with DM who seek to fast during Ramadan (N=569)

Sl	Risk element	Sc.	No. (%)	Sl	Risk element	Sc.	No. (%)
1. Type of diabetes mellitus				8. Macrovascular disease complications or comorbidities			
	Type 1 DM	1	4(0.7)		Unstable MVD	6.5	8(1.4)
	Others	0	565(99.3)		Stable MVD	2	96(16.9)
2. Duration of DM (years)					No MVD	0	465(81.7)
	≥ 10	1	181(31.8)	9. Renal impairment (eGFR)			
	< 10	0	388(68.2)		< 30 ml/min	6.5	11(1.9)
3. Presence of hypoglycemia					30 - 45 ml/min	4	35(6.2)
	Hypoglycemia unawareness	6.5	3(0.5)		45 - 60 ml/min	2	71(12.5)
	Recent severe hypoglycemia	5.5	18(3.2)		> 60 ml/min	0	452(79.4)
	Multiple weekly hypoglycemia	3.5	12(2.1)	10 Pregnancy			
	Hypoglycemia less than 1 time per week	1	53(9.3)		Pregnant not within targets	6.5	3(0.5)
	No hypoglycemia	0	483(84.9)		Pregnant within targets	3.5	1(0.2)
4. Level of glycemic control by HbA1c (%)					Not pregnant	0	565(99.3)
	> 9.0 (11.7 mmol/L)	2	222(39.0)	11. Frailty and cognitive function			
	7.5- 9.0(9.4 - 11.7 mmol/L)	1	171(30.1)		Impaired cognitive function or frail	6.5	10(1.8)
	< 7.5 (9.4 mmol/L)	0	176(30.9)		> 70 years with no home supports	3.5	14(2.5)
5. Type of treatment					No frailty or loss in cognitive functions	0	545(95.8)
	Multiple daily mixed insulin injections	3	219(38.5)	12. Physical labour			
	Basal bolus/insulin pump	2.5	34(6.0)		Highly intense physical labour	4	4(0.7)
	Once daily mixed insulin	2	30(5.3)		Moderate intense physical labour	2	14(2.5)
	Glibenclamide	1	1(0.2)		No physical labour	0	545(95.8)
	Gliclazide/ MR or Glimepiride or Repaglinide	0.5	177(31.1)	13. Previous ramadan experience			
	Others not on SU or insulin	0	108(19.0)		Overall negative experience	1	52(9.1)
6. Self-monitoring of blood glucose					No negative or positive experience	0	517(90.9)
	Indicated but not conducted	2	180(31.6)	14. Fasting hours			
	Indicated but conducted sub-optimally	1	222(39.0)		≥ 16 hours	1	0(0.0)
	Conducted as indicated	0	167(29.3)		< 16 hours	0	569(100.0)
7. Acute complications				Min, Max: 0, 25; median (IQR): 5.5 (3.5 – 8.0)			
	DKA/HONK in last 3 months	3	2(0.4)	DKA: Diabetic Ketoacidosis			
	DKA/HONK in last 6 months	2	5(0.9)	HONC: Hyperglycaemic Hyperosmolar Nonketotic Comae			
	DKA/HONK in last 12 months	1	9(1.6)	GFR: Estimated glomerular filtration rate			
	No DKA/HONK	0	553(97.2)	MVD: Macrovascular disease			

The risk category according to IDF-DAR guideline showed around 37.8%, 38.8% and 23.4% had high, moderate and low risk respectively. Despite knowing their risks of fasting, 88.8% of people with high risk and 96.8% of people with moderate risks still wished to fast (Figure-1).

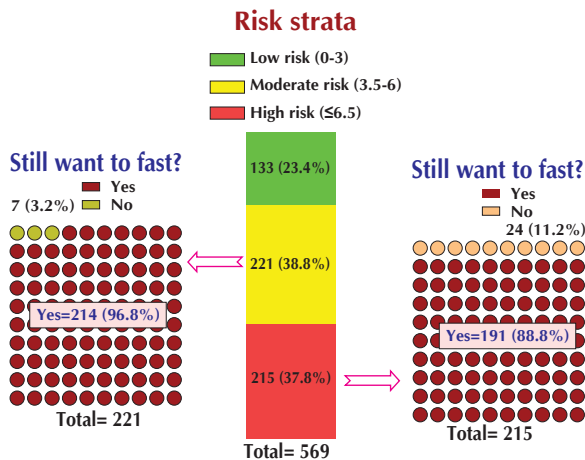


Figure-1: Risk category with people of DM who wish to fast and still wished to fast despite knowing their risk in moderate and severe category (N=569) Around 42% of participants were between the age range of 45 and 59 years. Nearly two-thirds of the study population was female. Most of the participants came from Dhaka, followed by Rajshahi and then Mymensingh division. Housewives and businessmen were the two most frequent occupations. Older people and the male sex had significantly higher risk scores. People from Chattagram than Rajshahi and housewife as well as service rather than other occupations (retired, unemployed, student, driver, etc.) had significantly higher risk scores. Similarly, percent of high-risk people was significantly higher with age ≥ 60 years and low-risk people were higher with age < 45 years. Percent of moderate-risk people was statistically higher than coming of other divisions (Rangpur, Khulna, Barishal, and Sylhet) (Table-II).

Table-II: Risk scores, category and wish to first according to different baseline characteristics (N=569)

Variables	Number (%)	Risk scores	p	Low risk	Moderate	High risk	p-Value
				(L) n=133	risk (M) n=221	(H) n=215	
Age group, years							
<45 (a)	167(29.3)	4.0(2.50-6.50)	<0.001 [†] c>b>a	61(36.5)	63(37.7)	43(25.7)	<0.001 [‡]
45 – 59 (b)	241(42.4)	5.0(3.50-7.0)		55(22.8)	98(40.7)	88(36.5)	La>Lc
≥ 60 (c)	161(28.3)	7.0(4.50-10.25)		17(10.6)	60(37.3)	84(52.2)	Ha<Hc
Sex							
Male	206(36.2)	6.0(3.50-8.63)	0.024*	44(21.4)	78(37.9)	84(40.8)	0.495 [‡]
Female	363(63.8)	5.0(3.50-8.0)		89(24.5)	143(39.4)	131(36.1)	
Residence (Division)							
Dhaka (a)	257(45.2)	6.0(3.0-8.0)	0.009 [†] b>c	65(25.3)	87(33.9)	105(40.9)	<0.001 [‡] Md>Me
Chattagram (b)	69(12.1)	6.0(4.0-9.0)		7(10.1)	28(40.6)	34(49.3)	
Rajshahi (c)	114(20.0)	4.50(2.50-7.0)		36(31.6)	46(40.4)	32(28.1)	
Mymensingh (d)	108(19.0)	5.0(3.50-7.0)		19(17.6)	56(51.9)	33(30.6)	
Others (e)	21(3.7)	7.0(3.0-9.0)		6(28.6)	4(19.0)	11(52.4)	
Occupation							
Housewife (a)	333(58.5)	5.0(3.50-8.0)	0.012 [†] a<d b<d	80(24.0)	131(39.3)	122(36.6)	0.087 [‡]
Businessman (b)	124(21.8)	5.0(2.50-8.0)		35(28.2)	41(33.1)	48(38.7)	
Service (c)	54(9.5)	5.25(3.50-6.63)		10(18.5)	28(51.9)	16(29.6)	
Others (d)	58(10.2)	6.0(4.50-11.0)		8(13.8)	21(36.2)	29(50.0)	

Within parentheses are percentages over row total for qualitative variable

Mann-Whitney U test* or Kruskal Wallis one way ANOVA with pairwise comparison by Dunn's test[†] was done for quantitative variables

Pearson's chi-square test with post hoc analysis[‡] was done for qualitative variables

Around 21% of the study population had at least one macrovascular complication of DM. The frequency of them was: ischemic heart disease (90, 19.4%), stroke (14, 3.0%), and peripheral arterial disease (3, 0.7%). On the other hand, about 40% of the study population had at least one microvascular complication. Diabetic neuropathy, diabetic kidney disease, and diabetic retinopathy were present in 25.9%, 17.7%, and 3.4% of the study population respectively. Only three participants had a complicated diabetic foot. Most of the participants had at least one other comorbidity including hypertension (49.3%), dyslipidemia

(9.0%), hypothyroidism (7.2%), nonalcoholic fatty liver disease (3.2%), and others. Half (206, 50.1%) of the study participants had high ALT (>40 U/L), and 86 (15.5%) had dipstick-positive proteinuria (Trace: 44, +: 34, 2+: 7, 3+: 1). Around 50% of them took only oral, 8% took only injectable and 41% took both types of antidiabetic drugs. Comparison of moderate-high risk populations who still wish to fast despite knowing their risks of fasting had a lower percent of macrovascular disease, lower creatinine levels with a lower percent of dipstick proteinuria, and use of less injectable antidiabetic medications. (Table-III).

Table-III: Baseline characteristics of people with moderate-high risk category who wish to fast despite their risk (n=440)

Variables	Total	Still wish to fast	Change decision	p-Value
No. (%)	569	407 (92.5)	33 (7.5)	
Age, years	50.97±12.02	52.24±11.75	53.27±15.73	0.714*
Female sex	363 (63.8)	258 (63.4)	19 (57.6)	0.506 [†]
Any macrovascular complication	104 (20.5) [507]	86 (23.2) [371]	12 (40.0) [30]	0.039 [†]
Any microvascular complication	224 (40.1) [559]	183 (45.5) [402]	19 (57.6)	0.182 [†]
Any other co-morbidity	343 (61.7) [556]	254 (63.2) [402]	24 (75.0) [32]	0.180 [†]
S. ALT, U/L	41.0 (32.0 – 54.0) [411]	42.0 (32.0-54.0) [299]	38.0 (32.0-48.0) [25]	0.488 [†]
S. creatinine, mg/dL	0.95 (0.81 – 1.11)	1.0 (0.83-1.20)	1.17 (0.97-2.18)	<0.001 [†]
Presence of dipstick proteinuria	86 (15.5) [556]	71 (17.8) [398]	12 (36.4)	0.010 [†]
HbA1C, %	8.50 (7.30 – 10.2)	8.90 (7.80-10.80)	8.51 (7.10-10.80)	0.317 [†]
Antidiabetics' routes				
Oral	287 (50.4)	153 (37.6)	11 (33.3)	
Injectable	47 (8.3)	37 (9.1)	8 (24.2)	0.021 [†]
Mixed	235 (41.3)	217 (53.3)	14 (42.4)	

Data were expressed in mean±SD/ median (IQR) or frequency (%) as appropriate. [Available no.]

Within (parentheses) are percentages over column total for qualitative variables and IQR for skewed numerical variables

Independent samples-T test*/ Mann Whitney U test[†] or Pearson's chi-square test[†] was done as appropriate

Discussion:

This observational study found that around 77% of the study population were at moderate-high risk for fasting. Despite knowing their risk, 92.5% of these at-risk populations still insisted on fasting. These population had relatively a lower risk profile when compared to people who changed their wishes. Risk scores also significantly differed by baseline characteristics. IDF-DAR Ramadan risk stratification is a simple and quick-to-administer calculator. However, it was criticized due to reliance more on expert opinion rather than evidence and without mentioning their level and grading. Besides, temperature and humidity were not considered which may be more important in tropical and subtropical countries.^{14,15} Despite these limitations, this is a major step in the management of DM patients who wish to fast. A recent DAR global survey reported that among 1054 patients with T1DM, 26.8% fasted for 30 days 60% developed hypoglycemia, 45% developed hyperglycemia, and 7% required emergency room visits or hospital admission. Although 1 in 4 participants could safely complete the full month of fasting, a significant portion had developed DM-related complications.¹⁶ So, individualization is necessary and a new criteria was proposed by Hussain et al (2020) for people with T1DM.¹⁷ Fortunately the prevalence of T1DM is low in our country. In our study, among four patients with T1DM, two had high, one had moderate and one had low risk. However, one patient with high risk and one patient with moderate risk consistently wished to fast. Previous studies reported from Bangladesh ensured safe fasting even in people with T1DM treated with conventional premix insulin with proper education and follow-up.⁹ The duration of DM in our patients was <10 years in 68.2% of the study population. A study from Malaysia reported that 69% of patients with a duration of DM \geq 10 years. In that study, the percent of high and moderate-risk patients was 40.5% and 33.3% respectively.¹⁴ In our study, the percentages of high and moderate cases were 37.8% and 38.8% respectively. It indicates that people with DM from our country had developed complications early and performed DM-related recommended practices worse than in Malaysia. Hypoglycemia is an important barrier to fasting. Interestingly, the frequency of hypoglycemia increased during Ramadan than before Ramadan mainly in people with T2DM rather than T1DM.^{18,19} However, hypoglycemia before Rama-

dan is associated with hypoglycemia during Ramadan with a higher frequency in those using insulin in people with T2DM.²⁰ Fortunately, only 15.1% of our study population had a history of hypoglycemia and most of them had less than one episode per week. Hypoglycemia is usually higher in T1DM and can interrupt fasting in around $\frac{1}{3}$ rd of patients.²¹ Among the persons who changed their wish to not fast after knowing the risks of fasting had a history of hypoglycemia and negative experience in previous Ramadan in 36.4% for both cases in our study. The Malaysian study reported 53% and 35.2% respectively.⁹ In our study, the main causes of changing their wish were an unstable macrovascular disease, advanced kidney disease, and the use of insulin. Hyperglycemia-related complications also increased during Ramadan. Only 2.9% of our study population had a history of hyperglycemia-associated complications in the previous one-year period. The DAR 2020 global survey found that 16.3% of T2DM patients developed hyperglycemia.¹⁸ However, 80% did not break the fast. On the other hand, hyperglycemia occurred in 44.8% of people with T1DM and was more common in the first week of Ramadan.¹⁹ Glycemic complications more commonly occurred in older persons (\geq 65 years) with T2DM and require more hospital care. These persons usually have a longer duration of DM, more macrovascular and microvascular complications and many have cognitive impairment.¹⁸ We also found higher risk scores in older persons with DM. Around 32% of our study population did not perform any SMBG at all. A previous study reported that around 37.5% did not perform SMBG during Ramadan.²² Insulin especially conventional premix regimen and sulfonylurea are associated with an increased risk of hypoglycemia. However, newer generation sulfonylurea is usually safe for fasting.²³⁻²⁵ In our study, around $\frac{1}{3}$ rd of patients were taking these safe sulfonylureas and 38.5% of people were taking premix insulin. Around 39% of the study population had very poor (>9%) and 30% (7.5%-9%) had poor glycemic control. However, poor glycemic control might not be a barrier to fasting even in people with T1DM.² The main strength of our study was the large study population with samples collected from different sites. The main limitations of this study were inadequate samples from some divisions of Bangladesh and we could not collect post-Ramadan follow-up data.

Conclusion:

Most of the Bangladeshi patients with DM who wished to fast had a moderate to high risk for fasting. Despite knowing the risks of fasting, more than 90% of patients still insisted on fasting. These patients' decisions should be respected and advised to take and follow medical advice to reduce their complications. The study findings may help clinicians as well as policymakers to take necessary steps for these vulnerable people. A study should be conducted throughout Bangladesh with data collected during and after Ramadan to validate the IDF-DAR risk calculator for the Bangladeshi population. This can also help to develop a population-specific risk calculator for Bangladeshi people with DM who wish to fast.

Conflict of interest:

None of the authors has any conflict of interest to declare

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