

## Research Article

# Changes in Metabolic Markers During Ramadan Fasting According to the IDF-DAR Risk Score 2021 in Patients with Type 1 and Type 2 Diabetes: A Multicentre Study in Algeria

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## Abstract

We aimed to assess changes in the metabolic markers of patients with diabetes between the pre-Ramadan and Ramadan periods according to the IDF-DAR risk stratification. We conducted a prospective observational study in 22 centres across Algeria. The IDF-DAR risk-stratification tool was used to categorize patients at the pre-Ramadan assessment.

A total of 1647 patients (1541 patients with type 2 diabetes and 106 patients with type 1 diabetes) were included. Of the 1324 patients who fasted, 42.1%, 26.9% and 31% were categorized as low-risk, moderate-risk and high-risk respectively. Hypoglycemia was more common in the high-risk (37.8%), compared with the moderate-risk (27.2%) and the low-risk (18.3%), p-value < 0.001. Compared with the pre-Ramadan period, during Ramadan glycemia increased by 33.6 ± 55.2 mg/dL in the low-risk category; 19.3 ± 60.6 mg/dL in the moderate-risk and 10.8 ± 70.9 mg/dL in the high-risk category, while the mean reduction in HbA1c was significantly higher in the high-risk category (-0.4 ± 2.4%) compared with the moderate-risk (-0.3 ± 2.2%) and low (0.3 ± 1.9%) categories.

**Conclusion:** Markers of glycemic control between the pre-Ramadan and Ramadan fasting periods varied according to the IDF-DAR risk categories with less favourable changes observed in the low-risk category.

**Keywords:** Diabetes, Ramadan, Metabolic markers

## Introduction

Fasting during Ramadan is an obligatory duty for Muslims as it is one of the five pillars of Islam. Ill people such as patients with diabetes are exempted from fasting. Diabetes is highly prevalent in the Middle East and North Africa where the majority of Muslims reside [1]. The highest prevalence of diabetes globally at 16.2% in 2021 was found in the Middle East and North Africa region. Of the 73 million people estimated to live with diabetes in Africa, 17 million were from North Africa [2]. Despite being exempted from fasting during Ramadan, many patients with diabetes choose to fast, sometimes against medical advice. Fasting during the month of Ramadan involves not eating or drinking anything from dawn to sunset. The duration of fasting depends on the period of the sacred month, and can range from 12 to 18 hours daily for 29 or 30 consecutive days. This prolonged fasting in patients with diabetes leads to an increased risk of adverse events such

as hypoglycemia, hyperglycemia and hospitalizations [3]. This risk is higher in patients with type 1 diabetes who tend to be on multiple injections of insulin treatment and in patients with type 2 diabetes on certain medications [4]. In 2021, the International Diabetes Federation (IDF) in collaboration with Diabetes and Ramadan (DAR) international alliance suggested a risk score to minimize the risk of complications during fasting for patients with diabetes (IDF-DAR 2021 risk stratification tool) [5]. This risk stratification tool categorizes patients with diabetes into three risk categories based on their likelihood of safely fasting during Ramadan with recommendations about fasting: Low-risk individuals (score of 0–3) are considered safe to fast; moderate-risk (score of 3.5–6) may fast with caution, and high-risk individuals (score of >6) should not fast. Previous studies show that high risk patients according to the IDF DAR 2021 risk stratification are more likely to present with adverse events especially

hypoglycemia during Ramadan fasting [6-8]. However, none of these studies reported on the changes in HbA1c a robust measure of glycemic control before and during Ramadan by IDF-DAR risk category. Moreover, it is unclear how the IDF-DAR 2021 guidelines are currently implemented in clinical settings by treating physicians and the patients' responsiveness to risk-category-based recommendations for fasting during Ramadan. In this large prospective study in Algeria, we aimed to assess the changes in metabolic parameters (markers of glycemic control, cholesterol and triglycerides levels) before and during Ramadan according to the different IDF-DAR risk categories in patients with type 1 and type 2 diabetes.

## Methods

### Study Design and Participants

This was a prospective hospital-based observational study conducted in 2021 in 22 counties, Algeria. Participants were adults aged above 18 years with type 1 diabetes or type 2 diabetes regardless of whether they intended to fast during Ramadan. Patients with any severe disorder needing special care were not included. Patients with cancer or any other severe illness requiring specific follow-up were not included. Inclusion of participants in this study started 6 weeks before Ramadan and ended one week before the beginning of Ramadan. Recruitment of participants into this study and data collection was done by their treating physicians which included general practitioners trained in diabetes management, and specialists working in the public or private sector who had previously received training on patients' education during Ramadan (training the trainers) been trained on pin the data collection.

Data for this study was collected using a pre-designed questionnaire administered using Google Forms in the pre-Ramadan and post-Ramadan periods.

### Ethical Approval

Ethical approval for this study was obtained from Setif University ethical committee and all participants provided written informed consent before inclusion.

### Pre-Ramadan Period

Patients were seen before Ramadan for a full assessment of their diabetes, complications and paraclinical check-up, as well as to receive therapeutic education focused on Ramadan in line with IDF-DAR recommendations (risk score, whether or not to fast, how to adapt their treatment, self-monitoring of blood glucose and how to stop fasting in the event of significant hyperglycemia or hypoglycemia). Specifically, data was collected on past medical history including type of diabetes and presence of comorbidities and current treatment, capacity of the patient to conduct Self-monitoring blood glucose (SMBG) and self-manage diabetes, experience during the previous Ramadan and all clinical and biological parameters included in the calculation of the risk score. This was used to categorize patients at the pre-Ramadan assessment into 3 categories of risk according to the IDF-DAR risk stratification tool: low-risk (score <3), moderate-risk (score 3.5–6) and high-risk (score >6). Anthropometric parameters

and the most recent biochemical data available were also collected. A second visit was scheduled after Ramadan for data collection on the fasting experience, complications and biochemical results available.

### Ramadan

During the Ramadan period which lasted 30 days, participants were contacted by phone by their treating physician to remind them about self-monitoring blood glucose and collect the recorded self-monitoring blood glucose (SMBG) results and data on the Ramadan fasting progress. Ramadan glycemia was obtained by calculating the mean of all glycemia recorded during the Ramadan fasting period.

### Post Ramadan Period

In the post-Ramadan period, data was collected on aspects related to fasting or no fasting reasons for breaking fasting, fasting experience, self-reported adverse events, SMBG results noted during Ramadan, 2-months post-Ramadan HbA1c noted

### Outcomes

Our primary outcome changes in HbA1c between the pre-Ramadan and post-Ramadan periods according to the IDF-DAR risk categories. Secondary outcomes were changes in glycemia, and lipid profile in the pre-Ramadan and post-Ramadan periods according to the IDF-DAR risk categories; and differences in the proportion of patients in the different risk categories who experienced adverse events.

### Statistical Analyses

Statistical analyses were performed using Stata 15. Descriptive statistics are presented as means and standard deviations  $\pm$  SD for continuous data (or median and [25th-75th percentile] for non-normally distributed continuous data) or numbers and percentages for categorical variables. We tested differences in means between the three risk categories using a one-way ANOVA (or differences in medians using the Kruskal Wallis test) and performed a Tukey's post hoc test for comparing the possible group pairings, when the ANOVA test was significant. Differences in proportions were tested using the chi-squared test. We also compared differences in changes in the metabolic parameters between the pre-Ramadan and Ramadan periods and derived linear trends across the risk categories by fitting linear regressions and including the IDF-DAR risk categories as an ordinal variable. Throughout, a p-value < 0.05 was considered statistically significant

## Results

### Baseline Characteristics of Participants

Table 1 shows the descriptive characteristics of participants stratified by risk score according to the IDF-DAR 2021 risk stratification tool. Using the IDF-DAR risk criteria at the pre-Ramadan assessment, 675(41%) were categorized as low-risk (score <3), 437(26.5%) as moderate-risk (score 3.5–6) and 535(32.5%) as high-risk (score >6). Of the 1647 participants with mean age  $57.8 \pm 12.7$  years, 57.3% were women. There was no difference in age and sex between participants in the different risk strata. The number of years of known diabetes

**Table 1:** Socio-demographic characteristics of study population by risk score (n=1647).

Characteristics	Low risk	Moderate risk	High risk	p-value
n (%)	675 (41)	437 (26.5)	535 (32.5)	
Age	57.5 ± 10.02	58.7 ± 11.68	57.5 ± 16.1	0.207
Sex				
Female, n(%)	377 (55.9)	257(58.8)	309(57.8)	0.598
Type 2 diabetes	673(99.7)	425(97.3)	443(82.8)	< 0.001
Duration diabetes (years)	5[2-8]	7[2-11]	8[4-13]	0.0001
Smoking				
No	648(96.0)	411(94.1)	487(91.0)	0.002
Yes	27(4.0)	26(6.0)	48(9.0)	
Education level, n(%)				
None	156(23.1)	127(29.1)	181(33.8)	0.007
Primary	159(23.7)	102(23.3)	110(20.6)	
Middle	113(16.7)	80(18.3)	83(15.5)	
Secondary	152(22.5)	81(18.5)	97(18.1)	
University	95(14.1)	47(10.8)	64(12.0)	
Marital status				
Single	06(0.9)	04(0.9)	16(3.0)	0.006
Lives with family	669(99.1)	433(99.1)	519(97.0)	
Profession, n(%)				
Unemployed	348(51.6)	229(52.5)	301(57.2)	0.01
Civil servant	117 (17.4)	61(14.0)	58(11.0)	
Faculty staff	02(0.3)	03(0.7)	08(1.5)	
Retired	170(25.2)	110(25.2)	125(23.8)	
Others	37(5.5)	33(7.6)	34(6.5)	
Authorized to fast	642(95.1)	284(64.1)	86(16.1)	
Intention to fast				
Will not fast	07(1.04)	44(10.1)	298(55.7)	< 0.001
Will fast	658(97.5)	365(83.5)	192(35.9)	
Don't know	10(1.5)	28(6.4)	45(8.4)	

**Table 2:** Clinical and biochemical characteristics of participants according to risk score (n=1647).

Characteristics	Low risk n=675	Moderate risk n=437	High risk n=535	p-value
Weight (Kg)	79.8 ± 13.6	81.1 ± 15.7	78.4 ± 14.6	0.01
BMI (Kg/m <sup>2</sup> )	29.2 ± 4.9	29.5 ± 5.5	28.6 ± 5.4	0.029
BMI categories				
Under weight	10(0.61)	2(1.89)	8(0.52)	< 0.001
Normal weight	341(20.70)	61(57.55)	280(18.17)	
Overweight	683(41.47)	27(25.47)	656(42.57)	
Obese	613(37.22)	16(15.09)	597(38.74)	
Waist circumference (cm)	100.6 ± 12.1	101.5 ± 14.0	99.1 ± 13.8	0.01
Systolic blood pressure (mmHg)	128.4 ± 13.7	130.6 ± 15.4	129.3 ± 16.9	0.08
Diastolic blood pressure (mmHg)	76.0 ± 8.7	76.3 ± 8.7	76.7 ± 9.5	0.32
Last HbA1c (%)	7.0 ± 1.1	7.8 ± 1.8	8.2 ± 1.9	< 0.0001
Mean glycemia pré-ramadan (mg/dL)	143.1 ± 32.9	157.2 ± 37.4	173.0 ± 48.9	< 0.0001
Number of days for glycemic measurement (days)				
3	392(58.1)	248(56.8)	289(54.0)	0.45
7	131(19.4)	104(23.8)	122(22.8)	
14	58 (8.9)	40(9.2)	52(9.7)	
30	51(7.3)	28(6.4)	40(7.5)	
90	43(6.4)	17(3.9)	32(6.0)	
GFR (ml/mn), n(%)				
≥90	350(51.9)	209(47.8)	207(38.7)	<0.001
60-89	322(47.7)	202(46.2)	180(33.6)	
45-59	03(0.4)	23(5.3)	92(17.2)	
30-44	0	03(0.7)	41(7.7)	
15-29	0	0	13(2.43)	
<15	0	0	2(0.37)	
Total cholesterol (mg/dL)	164.6 ± 40.0	163.9 ± 40.7	161.6 ± 43.9	0.44
HDL cholesterol (mg/dL)	42.3 ± 9.3	42.0 ± 8.9	42.0 ± 9.9	0.76
LDL cholesterol (mg/dL)	93.1 ± 31.2	93.9 ± 32.2	93.7 ± 33.9	0.89
Triglycerides (mg/dL)	144.3 ± 65.3	147.1 ± 69.3	146.6 ± 68.5	0.04

**Table 3:** Factors related to fasting in those who fasted (n=1324).

Characteristics	Low risk n=557	Moderate risk n=357	High risk n=410	p-value
n (%)				
Authorized to fast	528(94.8)	232(65.0)	77(18.8)	<0.001
Patient's initial decision				
Will not fast	06(1.08)	34(9.5)	215(52.4)	< 0.001
Will fast	543(97.5)	301(84.3)	161(39.3)	
Don't know	08(1.4)	22(6.2)	34(8.3)	
Fasted against medical advice	29(5.2)	125(35.0)	333(81.2)	< 0.001
Patient acted differently from initial decision	131(19.4)	126(28.8)	291(54.4)	< 0.001
Reasons for fasting, n (%)				
Don't know	11(1.97)	07(1.96)	25(6.1)	cfcfcc08(1.96)
Religious beliefs	155(27.8)	123(34.5)	117(28.6)	
Vertus du jeûne	16(2.87)	09(2.5)		
Scared of stigmatisation	1(0.18)	0	01(0.06)	< 0.001
Don't feel ill	1(0.18)	05(1.4)	08(1.96)	
Doctor authorized	05(0.90)	1(0.28)	0	
Religious beliefs + other reasons	368 (66.1)	212(59.4)	251(61.4)	
Fasted 30 days	346(62.1)	229(64.2)	200(48.8)	<0.001
Days fasted	30[25-30]	30[25-30]	29[21-30]	
Fasting broken	209(37.5)	128(35.9)	217(52.9)	<0.001
Reason for breaking fasting:				
Hypoglycemia				
Acute disease	11(1.6)	16(3.7)	31(5.8)	< 0.001
Hypoglycemia and acute disease	08(1.2)	01(0.2)	0	
	07(1.0)	02(0.5)	09(1.7)	
Hyperglycemia	0	0	0	< 0.001
Other complications	183(27.1)	109(24.9)	177(33.1)	

and the proportion of smokers was lower in the low risk category compared with the moderate and high-risk categories. A total of 1012 patients were authorized to fast by their treating physicians of which 63.4% in the low-risk category, 28.1% in the moderate risk category and 8.5% in the high risk category. More patients in the low risk category self-reported intending to fast compared with the moderate and high-risk category.

The clinical and biochemical characteristics of participants in the pre-Ramadan period are shown in Table 2. Last HbA1c and glycemia were lower in the low risk category compared with the moderate and high-risk categories. There was no difference in the cholesterol levels between the different strata.

### Fasting Practice and Complications

Of the 1647 participants included in this study, 1324 (80.4%) fasted (58.2% were women). Patients who fasted were significantly younger (57.5 ± 12.6 years) than patients who did not fast (59.2 ± 13.2 years), p-value = 0.026. There was no difference in sex or BMI between patients who fasted and those who did not fast. According to the IDF-DAR risk category, 42.1%, 26.9% and 31% of those who fasted were in the low, moderate and high-risk category respectively (Table 3).

Hypoglycemia was defined as blood glucose < 70 mg/dL; Hyperglycemia was defined as blood glucose > 300 mg/dL Overall 487 (36.8%) of those who fasted were not authorised to fast by their treating physician. 81.2% of patients who were not authorized to fast were in the high risk category, compared with 35% in the moderate

risk category and 5.2% in the low risk category (Table 3). Amongst those who fasted, 55.7% of those in the high-risk category had said they would not fast in the pre-Ramadan period compared with 10.1% in the moderate risk category and 1% in the low risk category (p-value < 0.001). 62.1%, 64.2% and 48.8% fasted for the full 30 days in the low risk, moderate and high-risk category respectively.

In addition, 43.4% of those with type 1 diabetes broke their fasting, compared with 33.0% of those with type 2 diabetes (p-value= 0.028). Regardless of the IDF-DAR risk category, 57.6% of the patients authorised to fast broke their fast compared with 37.0% of patients not authorised to fast (p-value = 0.02).

### SMBG: Self-Monitoring Blood Glucose

The median number of time points recommended for self-monitoring blood glucose during Ramadan was significantly higher for the high risk category 4 [4,5] compared with the low risk category 3 [2-4] (Table 4). There was no difference in the median number of time points of SBGM done during Ramadan between the categories. Mean HbA1c (2 months after Ramadan) was lower in the low risk category compared with the high-risk category. The number of glycemic results between 0.70 and 1.80 g/L was higher in the moderate category compared with the high-risk category. There was no difference in the mean of glycemia during Ramadan between the categories. A lower proportion of patients in the low risk category (18.3%) reported any hypoglycemia compared with the moderate (27.2%) and high-risk category (37.8%), and severe hypoglycemia was reported by 10.2%, 19.1% and 25.9% in the low, moderate and

high-risk category respectively. Hyperglycemia (> 3g/L) was also more prevalent in the high-risk category (48.8%) compared with the moderate (38.7%) and low risk category (35.0%). There was a difference between the categories in the how patients perceived their glycemia during Ramadan fasting. A higher proportion of patients in the high-risk category (52.9%) reported breaking their fast compared with the moderate (35.9%) and low risk (37.5%) categories (p-value < 0.001). The main reason for breaking fasting was hypoglycaemia. More patients in the low risk category reported following dietary advice, and having a good experience during Ramadan compared with those in the high-risk category (Table 5).

### Changes in Metabolic Parameters Before and During Ramadan

We also examined changes in metabolic parameters before and during Ramadan (Tables 6 and 7). Mean glycemia during Ramadan fasting was higher in the high-risk category than the low and moderate risk categories. Compared with the pre-Ramadan period mean glycemia was significantly higher during Ramadan fasting in all three categories. Being in the high-risk category was associated with a lower mean increase in glycemia ( $10.8 \pm 70.9$ mg/dL) compared with the moderate ( $19.3 \pm 60.6$  mg/dL) and low risk ( $33.6 \pm 55.2$  mg/dL) categories, p-value for linear trend < 0.001. The mean reduction in HbA1c was significantly higher in the high-risk category ( $-0.4 \pm 2.4\%$ ) compared with the moderate ( $-0.3 \pm 2.2\%$ ) and low ( $0.3 \pm 1.9\%$ ) risk categories. HDL cholesterol increased significantly in the high-risk category ( $1.7 \pm 13.1$  mg/dL) during Ramadan fasting compared with

Table 4: Glycemic control and complications during Ramadan in those who fasted.

Characteristics	Low risk n=557	Moderate risk n=357	High risk n=410	p-value
SMBG recommended	3[2-4]	4[3-5]	4[4-5]	< 0.001
SMBG done	1.4[1-2.2]	1.5[1.1-2.3]	1.6[1.2-2.5]	0.07
HbA1c 2 months after Ramadan	7.3 ± 1.5	7.5 ± 1.5	7.8 ± 1.7	< 0.001
Mean glycemia during Ramadan (mg/dL)	175.8 ± 46.8	175.3 ± 46.7	182.2 ± 54.4	0.07
Number of glycemia between 0.70 and 1.80 g/L	23.4[16.8-35.1]	24.9[18-37.8]	23.4[16.0-32.0]	0.006
Total number of glycemia during Ramadan	38[27-51]	41[30-58]	40[30-58]	0.01
Total hypoglycemia	102(18.3)	97(27.2)	155 (37.8)	< 0.001
Symptomatic hypoglycemia	87(15.6)	88(24.7)	152(37.1)	< 0.001
Documented hypoglycemia	118(21.2)	79(22.1)	410(30.4)	< 0.001
Severe hypoglycemia	57(10.2)	68(19.1)	106(25.9)	< 0.001
Hyperglycemia > 3 g/L	195(35.0)	138(38.7)	200(48.8)	< 0.001
Hospitalisation n(%)				
No	546(98.0)	346(96.9)	385(94.1)	
Ketosis coma	02(0.36)	01(0.28)	03(0.73)	
COVID 19 infection	06(1.08)	07(1.96)	11(2.69)	
Infection	02(0.36)	01(0.28)	02(0.49)	0.115
Hyperosmolar coma	0	0	03(0.73)	
Acute condition	01(0.18)	0	0	
Diabetic foot	0	02(0.56)	04(0.98)	
Others	0	0	01(0.24)	
Perception about glycemia				
Within normal range	436(78.4)	269(75.4)	290(70.7)	
High	81(14.6)	62(17.4)	78(19.0)	0.14
Too high	10(1.8)	09(2.5)	16(3.9)	
Don't know	29(5.2)	17(4.8)	26(6.3)	

**Table 5:** Dietary adherence and experience during Ramadan according to the risk score (n=1324).

Characteristic	Low risk n(%)	Moderate risk n(%)	High risk n(%)	p-value
Did you follow dietary advice				
No	84(15.1)	63(17.7)	84(20.5)	0.03
Yes	428(76.8)	268(75.1)	279(68.2)	
Don't know	45(8.1)	26(7.3)	46(11.3)	
How many meals per day?				
2	539(96.8)	341(95.5)	385(93.9)	0.18
3	18(3.2)	16(4.5)	24(5.9)	
4	0	0	1(0.2)	
Family support in following dietary advice				
No	168(30.2)	98(27.5)	150(36.6)	0.035
Yes	360(64.6)	242(67.8)	234(57.1)	
Don't know	29(5.2)	17(4.8)	26(6.3)	
Experience during Ramadan				
Good	447(80)	263(73.9)	273(67.2)	0.001
Fair	37(6.6)	33(9.3)	47(11.6)	
Bad	45(8.1)	41(11.5)	59(14.5)	
Don't know	30(5.4)	19(5.3)	27(6.7)	

**Table 6:** Change in metabolic parameters before and after Ramadan in the different risk categories in those who fasted (n=1324).

Markers	Pre-Ramadan Mean ± SD	Post Ramadan Mean ± SD	Mean difference 95 % [CI]	p-value
Low risk				
Glycemia (mg/dL)	142.1 ± 32.1	175.8 ± 46.8	33.6 ± 55.2	< 0.0001
HbA1c (%)	7.0 ± 1.1	7.3 ± 1.5	0.3 ± 1.9	< 0.0001
Total cholesterol (mg/dL)	163.2 ± 39.0	163.9 ± 46.2	0.7 ± 43.4	0.69
HDL cholesterol (mg/dL)	42.2 ± 0.4	41.8 ± 10.0	-0.4 ± 12.3	0.42
LDL cholesterol (mg/dL)	92.2 ± 30.1	97.8 ± 41.8	5.7 ± 40.9	0.001
Triglycerides (mg/dL)	143.5 ± 64.4	142.1 ± 67.3	-1.5 ± 66.8	0.61
Moderate risk				
Glycemia (mg/dL)	155.9 ± 38.2	175.3 ± 46.7	19.3 ± 60.6	< 0.0001
HbA1c (%)	7.8 ± 1.8	7.5 ± 1.5	-0.3 ± 2.2	0.003
Total cholesterol (mg/dL)	165.0 ± 40.8	163.6 ± 46.9	-1.4 ± 45.2	0.56
HDL cholesterol (mg/dL)	42.1 ± 8.7	40.8 ± 9.6	-1.4 ± 12.4	0.03
LDL cholesterol (mg/dL)	94.4 ± 32.1	96.9 ± 39.6	2.5 ± 39.7	0.23
Triglycerides (mg/dL)	148.3 ± 71.4	144.8 ± 68.0	-3.5 ± 69.9	0.34
High risk				
Glycemia (mg/dL)	171.4 ± 48.3	182 ± 54.4	10.8 ± 70.9	0.002
HbA1c (%)	8.2 ± 1.9	7.8 ± 1.7	-0.4 ± 2.4	0.0008
Total cholesterol (mg/dL)	162.0 ± 45.8	167.3 ± 51.4	5.3 ± 45.9	0.02
HDL cholesterol (mg/dL)	41.9 ± 9.9	43.6 ± 11.9	1.7 ± 13.1	0.007
LDL cholesterol (mg/dL)	93.0 ± 2.1	98.2 ± 42.1	5.2 ± 41.8	0.01
Triglycerides (mg/dL)	145.5 ± 64.6	150.7 ± 67.0	5.2 ± 71.0	0.14

**Table 7:** Comparison of changes in metabolic parameters before and after Ramadan between the different risk categories (n=1324).

Markers	Low risk Mean difference (95% CI)	Moderate risk Mean difference (95% CI)	High risk Mean difference (95% CI)	p-value for linear trend
Glycemia (mg/dL)	33.7(29.1, 38.3)	19.3(13.0, 25.7)	10.9(4.0, 17.8)	< 0.001
HbA1c (%)	0.3(0.2, 0.5)	-0.3(-0.6, -0.1)	-0.4(-0.6, -0.2)	0.001
Total cholesterol (mg/dL)	0.7(-2.9, 4.4)	-1.4(-6.1, 3.3)	5.3(0.8, 9.7)	0.12
HDL cholesterol (mg/dL)	-0.4(-1.4, 0.6)	-1.4(-2.7, -0.1)	1.7(0.5, 3.0)	0.008
LDL cholesterol (mg/dL)	5.7(2.2, 9.1)	2.5(-1.6, 6.6)	5.2(1.2, 9.3)	0.87
Triglycerides (mg/dL)	-1.5(-7.0, 4.1)	-3.5(-10.8, 3.8)	5.2(-1.7, 12.1)	0.14



the pre-Ramadan period. Still, there was no evidence of a significant difference in the low and moderate categories. Total cholesterol and LDL cholesterol did not change during Ramadan compared with the pre-Ramadan period in any of the categories.

## Discussion

In this prospective observational study including 1647 patients living with diabetes recruited from outpatient private and public clinics in the public and private healthcare sectors in Algeria, we showed differences in metabolic parameters according to risk categories during the Ramadan fasting compared to the pre-Ramadan period. Specifically, we observed that changes in glycemic markers and cholesterol levels between the pre-Ramadan and Ramadan fasting periods varied by risk categories. Our study reinforces the importance of applying the risk score and of understanding the impact of fasting on biological parameters, notably glycaemic and lipid balance. Our study showed a higher proportion of smokers in the high-risk category compared with the low and moderate risks. The presence of a cardiovascular disease is one of the IDF-DAR criteria for severity and smoking is a major risk factor for CVD [9]. Therefore, the higher proportion of smokers in the high-risk category may be reflective of their CVD state. Our findings showed that there has been improvement in the application of the IDF-DAR recommendations for fasting according to the risk categories by the treating physicians. While our study shows that 16% of patients in the high-risk category were authorized to fast, this represents an improvement as our previous study in 2017 showed that up to 43.2% of the patients were authorized to fast [10]. Despite this, 36% of the patients in the high-risk category reported intending to fast. Ramadan fasting is of significant importance to many Muslims and although religious beliefs was the major reason reported in our study shows that there are other reasons why Muslims choose to fast beyond religious beliefs. However, in the low risk category, 642 patients were authorised to fast, but only 557 patients fasted, whereas up to 77% of patients in the high risk group fasted. In the two previous situations, our hypothesis is that these 2 changes may be linked to parameters not covered by the current score, which may overestimate or underestimate the risk score. We observed that patients in the high-risk category were more likely to break their fast compared with those in the low and moderate category and the leading factor associated with breaking fasting was hypoglycemia. This is consistent with previous studies showing that patients in the high-risk category are ~ 8 fold more likely to develop adverse events than those in the low risk category [6]. Overall, the proportions of patients in the high-risk category reporting hypoglycemic events (total, symptomatic or severe hypoglycaemia) were significantly higher in the high-risk category than the moderate and low risk category. However, about half of patients in the high-risk category were able to fast for the full 30 days. This suggests that the education provided to patients may have been effective with a high proportion of patients even in the high-risk category being able to fast safely and improve glycemic control. Patients in the high risk category presented with a poorer metabolic profile during Ramadan than the moderate and low risk categories. Specifically, glycemia, HbA1c, total and LDL cholesterol and triglycerides were higher in the high-risk category, than in the low and moderate risks categories. Also, mean changes between the

Ramadan and pre-Ramadan periods were higher in the low risk categories than in the high and moderate risks. For instance, HbA1c significantly increased in the low risk categories, while it dropped in the moderate and high risk categories. Previous studies reporting the changes in metabolic parameters before and during Ramadan fasting show mixed results with some studies showing a better metabolic profile during Ramadan [11,12] than before Ramadan and others showing a worse metabolic profile or no difference [10-14]. However, these studies did not examine the metabolic changes according to risk levels. Therefore, it is possible that the beneficial effects observed during Ramadan were driven by the patients in the high-risk category whose metabolic baseline parameters tend to be very poor.

## Strengths and Limitations

This is the largest prospective study to date in patients with diabetes comparing the metabolic parameters of patients before and during Ramadan fasting according to the IDF-DAR risk categories. Patients were recruited by probability sampling from many centres (both private and public healthcare sector) leading to high external validity. We did not record any lost-to-follow up as we used lessons learned from our previous study in this population to ensure high retention. We recorded 2 months post-Ramadan HbA1c a robust measure of glycemic control and compared it with the pre-Ramadan HbA1c. Despite these strengths, the main limitation of our study resides in the lack of a control arm. Therefore it is unclear whether the changes observed in the post Ramadan period are associated with Ramadan fasting, or the education provided or both. In addition, complications recorded in this study such as hypoglycemic events were self-reported which may be subject to recall bias and social desirability bias leading to misclassification. Lastly, post-Ramadan data collection happened by telephone call due to the COVID-19 pandemic.

## Conclusion

In this study, we showed that metabolic control during Ramadan varied according to the IDF-DAR risk categories, with worse metabolic parameters during Ramadan in the high-risk category than in the moderate and low risks categories. However, mean changes in glycemia and HbA1c between the pre-Ramadan period and during Ramadan (2 months post-Ramadan for HbA1c) were less favourable in the low risk category compared with the moderate and high risk categories, suggesting that patients in the low risk category may also benefit from monitoring during Ramadan fasting. Still, a high proportion of patients in all 3 risk categories including the high-risk category were able to fast for all the 30 days suggesting that the education provided in the pre-Ramadan period may have been effective. Concerning the change of mind of patients authorized or not to fast, and according to their risk score, the work of pre-Ramadan education remains important, but it could be that revaluations or the addition of certain risk score parameters would provide some solutions.

## Declarations of Interest

None

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