

Comparison between High- and Low-Risk Diabetic Patients Who Fast Ramadan: A Prospective Cohort Study

Abdulwahab Elbarsha^{1,2}, Maisoon Elhemri¹, Rafik Elmehdawi^{1,2}

¹Department of Medicine, Benghazi Medical Center, ²Department of Medicine, Faculty of Medicine, University of Benghazi, Benghazi, Libya

Abstract

Objectives: The aim of this study is to compare the low-risk patients with the high- and very high-risk patients who choose to fast during Ramadan regarding the rates of breakfasting, hypoglycemia, hyperglycemia, hospitalization, and death. **Patients and Methods:** This is an observational, analytic, 1-month prospective, cohort study that involved patients with diabetes mellitus who choose to fast during the month of Ramadan in the Muslim year 1437. The patients were divided into two cohorts: Cohort 1 (high-risk) consisted of 83 patients who were categorized as high/very high-risk according to the International Diabetes Federation–Diabetes and Ramadan International Alliance guidelines on diabetes and Ramadan and Cohort 2 (low-risk) consisted of 65 patients categorized as moderate/low risk. **Results:** The overall of whole month fasting rate was 88% (100% in the low-risk group and 79% in the high-risk group, $P = 0.000$), and the rate of hypoglycemia was 12% (20.9% in the high-risk group vs. 0% in the low-risk group, $P = 0.002$). The rate of severe hyperglycemia was 7.7% (13.5% in the high-risk group vs. 0% in the low-risk group, $P = 0.14$). **Conclusions:** Patients in the high-risk category were significantly more likely to breakfasting during Ramadan than those in the low-risk category. Hypoglycemia was significantly higher in the high-risk group. The rates of severe hyperglycemia, hospitalization, and presumed mortality were not significantly higher in the high-risk group.

Keywords: Hypoglycemia, Ramadan fasting, risk stratification

INTRODUCTION

Religious scholars and physicians have agreed that people with diabetes may be exempted from fasting if it is likely to put them risk from worsening of health or delay in healing.^[1,2] Several guidelines recommended making a formal assessment of the risk for all diabetic patients before Ramadan.^[3-5] For instance, the International Diabetes

Federation (IDF)–Diabetes and Ramadan (DAR) International Alliance guidelines on diabetes and

Address for correspondence: Dr. Rafik Elmehdawi,
Department of Medicine, Benghazi Medical Center, Benghazi, Libya.
E-mail: rafikal2002@yahoo.com

Submitted: 04-Jan-2020 **Revised:** 30-Aug-2020
Accepted: 31-Aug-2020 **Published:** 26-Sep-2020

Access this article online

Quick Response Code:



Website:
www.ijmbs.org

DOI:
10.4103/ijmbs.ijmbs_2_20

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How to cite this article: Elbarsha A, Elhemri M, Elmehdawi R. Comparison between high- and low-risk diabetic patients who fast Ramadan: A prospective cohort study. *Ibnosina J Med Biomed Sci* 2020;12:208-14.

Ramadan proposed three risk categories for patients with diabetes who will observe fasting during the month of Ramadan, and these categories are very high, high, and low.^[5]

The very high- and high-risk categories include those with acute illnesses, older patients with ill health, patients with poorly controlled diabetes, patients with history of recurrent hypoglycemia, hypoglycemia unawareness, or recent history of hyperglycemic emergencies, patients with type 1 diabetes, patients with stable or unstable macrovascular complications, type 2 diabetes patients treated with multiple-dose injection or mixed insulin, patients with chronic kidney disease (CKD) stages ≥ 3 , patients with other comorbid conditions that represent additional risk factors, pregnant women with preexisting diabetes, or gestational diabetes mellitus treated with insulin, sulfonylurea, metformin, or lifestyle, people with diabetes and performing intense physical labor, and persons treated with drugs that may affect cognitive function.

According to the IDF-DAR Practical Guidelines, patients who are in the two highest categories (very high and high) should not fast.^[5] As some patients may insist on fasting against medical advice,^[6-8] individualization of care based on risk assessment is crucial^[9] and preparedness of physicians to undertake this role effectively is of paramount importance.^[9,10] We have undertaken this exercise to compare patients with low risk with those with high and very high risk who are undertaking the fasting during Ramadan.

PATIENTS AND METHODS

Objectives

The aim of this study is to compare the low-risk patients with the high- and very high-risk patients who choose to fast during Ramadan regarding the rates of breakfasting, hypoglycemia, hyperglycemia, hospitalization, and death.

Design

This is an observational, analytic, 1-month prospective, cohort study that involved patients with diabetes mellitus who choose to fast during the month of Ramadan in the Muslim year 1437.

During this year, Ramadan (the 9th month of Islamic calendar) started on May 27 and ended on June 24, 2017. We enrolled 148 consecutive adult patients with diabetes who were attending the diabetes clinic at Benghazi Medical Center for pre-Ramadan visits and chose to fast. The patients were divided into two cohorts: Cohort 1 consisted of 83 patients who were categorized as high/very high-risk according to the IDF-DAR International Alliance guidelines on diabetes and Ramadan and Cohort 2 consisted of 65 patients categorized as moderate/low risk. The IDF-DAR recommendation on diabetes and Ramadan was adopted by the treating doctors.

Outcome measures

The data were collected over two stages: Stage 1 at pre-Ramadan visit which took place within 6 weeks before Ramadan and Stage 2 at post-Ramadan visits which took place within 4 weeks post-Ramadan. Data collection included demographic data, type of treatment during Ramadan, use of self-monitoring of blood glucose (SMBG), the level of hemoglobin A1C (HbA1c) within 3 months of the start of Ramadan, and after Ramadan, number of days in which patient broke the fast, frequency of hypoglycemia, hyperglycemia, and diabetic ketoacidosis (DKA), and frequency of hospitalization during Ramadan. Our primary endpoints were fasting rate, mortality rate, hospitalization rate, rate of hypoglycemia, and rate of severe hyperglycemia. The secondary endpoint was the change in HbA1C level after Ramadan fasting. Hypoglycemia was defined as symptoms that were perceived by the patient as hypoglycemia and urged him/her to breakfast with or without documented low blood glucose, and it was categorized as severe or mild. A severe hypoglycemic episode was defined as the episode that could not be treated by the patient alone but required assistance from another person. Mild hypoglycemia was defined as a hypoglycemic episode that was treated by the person with diabetes alone without need for assistance. Severe hyperglycemia was defined as a self-reported blood glucose level ≥ 300 mg/dl.

Statistical analysis

Data were analyzed using IBM SPSS (statistical program for social science version) version 23.0

(IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp). Chi-square test, paired and unpaired *t*-test, and Mann–Whitney U-test were used in statistical analysis. $P < 0.05$ was considered statistically significant.

RESULTS

Characteristics of the study population

Out of the 148 enrolled patients, 64% were females, 83% had type 2 diabetes mellitus (DM) and 16.2% had type 1 DM, the mean age of participants was 52.21 ± 14.79 years (18–84), and the mean duration of diabetes was 9.28 ± 7.6 years (1–37). 6.4% of the patients had CKD Stage 3, 12.8% had stable macrovascular complication, 2% had a history of acute coronary syndrome within the last 6 months before Ramadan, and 2.7% were using drugs that may affect their cognitive function [Table 1]. About 43% of the patients (60/142) were treated with different insulin regimens (basal, mixed, or basal bolus) during Ramadan. About 16.21%, 1.35%, and 0.67% of the patients had a history of recurrent hypoglycemia, severe hypoglycemia, and hypoglycemia unawareness, respectively, in the last 3 months before Ramadan. The HbA1c

results within the last 3 months before Ramadan were available for about 98% of the patients with the mean HbA1c $7.7\% \pm 1.6\%$ (4.9–12.8), 33.8% with HbA1c $<7\%$, 24.8% with HbA1c 7%–7.9%, 22.75% with HbA1c 8%–8.9%, 9.65% with HbA1c 9%–9.9%, and 8.96% with HbA1c $\geq 10\%$. Only 29% of the patients were doing SMBG during Ramadan.

Interruption of fasting

Of the total 4118 fasting days (29 days \times 142 patients), the patients in the study managed to fast 4087 days (99.24%). The mean of fasted days was 28.78 ± 0.75 (23–29) days for the whole group (28.62 ± 0.96 days in the high-risk group and 29 days in the low-risk group, $P = 0.002$) [Table 2]. About 88% of all patients completed 29 days of fasting (100% in the low-risk group and 79% in the high-risk group, $P = 0.000$), 17 patients break the fast for ≥ 1 day, and all of them were in the high-risk group. The total unfasted days were 31 days. More than 90% of the patients who broke fast did so because of acute metabolic decompensation. The most common cause of breakfasting was hypoglycemia (54.8%), followed by hyperglycemia (35.5%), and other causes of breakfasting included excessive thirst

Table 1: The demographic, clinical treatment, and fasting practices of the whole group and of the high-risk versus low-risk patients

Characteristics	All	Low risk	High risk	P
Total number	148	62	86	-
Males	53	18 (29%)	35 (40.69%)	0.16
Females	95	44	51	
Mean age	52.2 ± 14.8 (18-84)	54.3 ± 12.8 (32-84)	50.7 ± 15.9 (18-83)	0.14
Type 1	24	0	24	-
Type 2	123	62	61	-
Secondary diabetes	1	0	1	-
Mean DM duration	9.3 ± 7.6 (1-37)	6.2 ± 5.4 (1-27)	11.5 ± 8.18 (1-37)	0.000
Doing SMBG (%)	40 (29.4)	9 (15.25%)	31 (39.7)	0.002
Basal-bolus insulin (%)	47 (31.97)	0	47 (54.65)	-
Premixed insulin (%)	12 (8.16)	0	12 (13.95)	-
Metformin + basal insulin (%)	4 (2.72)	2 (3.22)	2 (2.32)	-
Metformin (%)	34 (23.12)	26 (41.93)	8 (9.30)	-
Metformin + DPP4 Inhibitors (%)	6 (4.08)	5 (8.06)	1 (1.16)	-
Metformin + Sulphonylurea (%)	35 (23.64)	21 (33.87)	14 (16.27)	-
Sulphonylurea (%)	4 (2.72)	3 (4.83)	1 (1.16)	-
Sulphonylurea + DPP4 Inhibitors (%)	3 (2.04)	2 (3.22)	1 (1.16)	-
Lifestyle (%)	3 (2.04)	3 (4.83)	0	-
Pre-Ramadan HbA1c	7.7 ± 1.5 (4.9-12.8)	7.14 ± 1.2 (4.9-9.9)	8.18 ± 1.7 (5.2-12.8)	0.000

Independent-samples Mann–Whitney U-test and Chi-square test. DM: Diabetes mellitus, SMBG: Self-monitoring of blood glucose, HbA1c: Hemoglobin A1C

Table 2: The outcomes of the whole group and the high-risk vs. low-risk patients

Outcome measures	All	Low risk	High risk	P
Dropout rate (%)	4/148 (2.7)	1/62 (1.61)	3/86 (3.48)	0.64
Mean A1c after	7.8±1.4 (5.4-12.6)	7.1±1.1 (5.4-12)	8.3±1.3 (5.8-12.6)	0.000
Patient fasted 29 days	88.02 (125/142)	100% (61/61)	79% (64/81)	0.000
Mean fasted days	28.8±0.8 (23-29)	29	28.6±1.0 (23-29)	0.002
Total days not fasted	31	0	31	0.000
Days not fasted	-	0	1.82±1.38 (1-6)	0.000
Mild hypoglycemia (%)	8.45	0	14.8	0.094
Severe hypoglycemia (%)	3.5	0	6.1	0.31
Any hypoglycemia (%)	12	0	20.9	0.002
Severe hyperglycemia (%)	7.74	0	13.5	0.14
Presumed mortality (%)	3 (2.02)	0/62	3/86 (3.48)	0.26

Independent-samples Mann–Whitney U test and Chi-square test

without hyperglycemia (2 days) and severe headache (1 day). 26.6% of patients who were treated with insulin broke fast in comparison to 1.23% of the patients who were treated with oral hypoglycemic drugs, $P = 0.000$, odds ratio: 21.6.

Hospitalization and mortality

One patient was hospitalized during the study period because of one episode of severe hypoglycemia. 97.3% of the study patients appeared for follow-up after Ramadan, however, 4 patients (3 – high risk and 1 – low risk) defaulted, and therefore, it is not known whether they are dead or alive; for the sake of statistical measurements, we presumed that the 3 patients in the high-risk group have died and the other 1 in the low-risk group survived Ramadan fasting, and this gave an estimated mortality rate of 2.02% in the whole group (3.48% in the high risk and 0% in the low risk, $P = 0.26$) [Table 2].

Hypoglycemia

During Ramadan, 12% of the patients reported at least 1 episode of hypoglycemia (1–3) (20.9% in the high risk vs. 0% in the low risk, $P = 0.002$) [Table 3]. Most of the episodes (70.4%) were mild. Out of the total 4118 fasting days, there were 17 days (0.41%) without fasting because of hypoglycemia. All hypoglycemic episodes happened in patients treated with insulin (10 on basal-bolus regimen, 6 on premixed insulin, and 1 on basal insulin plus 2 oral antihyperglycemic drugs). The rate of hypoglycemic episodes was significantly higher in patients treated with insulin in comparison to noninsulin therapy (18.33% vs. 0%, $P = 0.000$). Only one patient was hospitalized during the

Table 3: Frequency of hypoglycemia and hyperglycemia in the whole study group and high- and low-risk subgroups during Ramadan*

	All Patients	High risk	Low risk	P
Mild hypoglycemia	12/142	12/ 81	0	0.094
Severe hypoglycemia	5/142	5/ 81	0	0.31
Any hypoglycemia	17/142	17/81	0	0.002
Severe hyperglycemia	11/142	11/81	0	0.14

*Episodes/patients

study period because of one episode of severe hypoglycemia.

Hyperglycemia

During Ramadan, 7.7% of the patients reported at least 1 episode of severe hyperglycemia.^[1-4] The patients in the high-risk group developed much more hyperglycemic episodes than in the low-risk group, but that was not statistically significant (13.5% vs. 0%, $P = 0.14$) [Table 2]. Hyperglycemia >300 mg/dl was the second leading cause of breakfasting (35.5%), but no single episode of DKA or hyperosmolar hyperglycemic state (HHS) occurred in the study group. All hyperglycemic episodes happened in patients treated with insulin (10 on basal-bolus regimen and 1 on premixed insulin). The rate of hyperglycemic episodes was significantly higher in patients treated with insulin in comparison to noninsulin therapy (8.33% vs. 0%, $P = 0.008$).

Changes in hemoglobin A1C

The patients in the high-risk group had significantly higher mean HbA1C than those in the low-risk group both before and after Ramadan fasting [Table 4]. However, in both the groups, there was no significant

change in the mean HbA1C after Ramadan fasting. Moreover, the distribution of the mean HbA1C difference was the same across high- and low-risk categories (0.1 vs. -0.05, $P = 0.16$).

Predictors of the outcomes

Out of the multiple risk factors that were used in this study to categorize patients as high risk for fasting, three risk factors could significantly predict that patients will break the fast [Table 5]. Firstly, type of treatment; being treated with insulin ($P = 0.000$). Among the 17 patients who broke fast, 16 were on insulin (9 were on basal-bolus regimen, 6 were on premixed insulin, 1 on basal insulin, and 1 on metformin). Secondly, type of diabetes; having type 1 DM (among the 17 patients who broke fast, 9 had DM1 and 8 had DM2. Thirdly, HbA1c of 7% or more before Ramadan; among the 17 patients who broke fast 14 had HbA1c of 7% or higher.

DISCUSSION

About 88% of all patients in this study successfully fasted the whole month of Ramadan (100% in the low-risk group and 79% in the high-risk group, $P = 0.000$), and this is much higher than the 64% reported by the CREED study^[7] and even higher than what we have reported 10 years back from the same city.^[8] This differences could be explained by the fact that during the last decade, a lot of studies in this field have been published and new guidelines have been developed the things that might have been contributing to the improvement in patients' management before and during Ramadan and hence a higher rate of successful full month fasting. The mean of fasted days was significantly higher in the low-risk group (29 days vs. 28.62 ± 0.96 days, $P = 0.002$) because all the 17 patients who broke the fast for ≥ 1 day were in the high-risk group. Like in the previous report,^[8] most of the patients who broke fast in this study (~90%) did so because of acute metabolic decompensation, and the most common cause of breakfasting was hypoglycemia (54.8%), followed by hyperglycemia (35.5%). Ninety-four percent of the patients who broke fasting were treated with insulin. Patients treated with insulin were 22 times more likely to breakfasting during Ramadan than patients treated with noninsulin therapies.

Table 4: Values of the mean hemoglobin A1C before and after Ramadan in the whole study group and high- and low-risk subgroups

HbA1c values	All patients	Low risk	High risk
Before Ramadan	7.7 \pm 1.5	7.14 \pm 1.2 (4.9-9.9)	8.18 \pm 1.7 (5.2-12.8)
After Ramadan	7.8 \pm 1.4	7.1 \pm 1.1 (5.4-12)	8.3 \pm 1.3 (5.8-12.6)
<i>P</i> *	0.51	0.54	0.17

*Paired sample *t*-test. HbA1c: Hemoglobin A1C

Table 5: Predictors of hypoglycemia, hyperglycemia, and breaking of the fast

Parameters	Hyperglycemia (%)	Hypoglycemia (%)	Breaking of fasting (%)
Type of diabetes			
DM1	3/24 (12.5)	7/24 (29.16)	9/24 (37.5)
DM 2	2/118 (1.69)	4/118 (3.38)	8/118 (6.77)
<i>P</i>	0.034	0.000	0.000
Type of therapy			
Insulin	5/60 (8.3)	11/60 (18.3)	16/60 (26.7)
Noninsulin	0/82	0/82	1/82 (1.21)
<i>P</i>	0.008	0.000	0.000
Recurrent hypoglycemia			
Yes	1/22 (4.5)	1/22 (4.5)	2/22 (9)
No	4/120 (3.3)	10/120 (8.3)	15/120 (12.5)
<i>P</i>	0.77	0.54	0.65
Stage of CKD			
CKD-3	0/9	0/9	0/9
CKD-1/2	4/126 (3.2)	9/126 (7.1)	15/111 (13.5)
<i>P</i>	1.0	1	0.59
Baseline HbA1c level			
<7%	0/47	0/47	1/47 (2.1)
$\geq 7\%$	5/95 (5.2)	11/95 (11.5)	16/95 (16.8)
<i>P</i>	0.17	0.016	0.012

CKD: Chronic kidney disease, DM: Diabetes mellitus, HbA1c: Hemoglobin A1C

During Ramadan, 12% of the patients reported at least 1 episode of hypoglycemia,^[6-8] which is higher than what was reported by the CREED study^[3] but much less than what we previously reported from the same city (31%).^[7] The patients in the high-risk group developed significantly much more hypoglycemic episodes than in the low-risk group (20.9% vs. 0%, $P = 0.002$), which is explained by the fact that this group includes patients with type 1 DM and most of the patients who were treated with insulin, and this puts them at a higher risk of hypoglycemia. All hypoglycemic episodes happened in patients treated with insulin (10 on basal-bolus regimen, 6 on

premixed insulin, and 1 on basal insulin plus 2 oral antihyperglycemic drugs) which is not unexpected. Hospitalization during Ramadan was rare, as only one patient needed hospitalization during Ramadan because of hypoglycemia.

Libya is a country with a high prevalence of type 2 diabetes.^[11] Furthermore, fasting is practiced universally by the adult Muslim native population which makes our center very suitable to conduct the present study. During Ramadan, 7.7% of the patients reported at least 1 episode of severe hyperglycemia.^[1-4] The incidence of hyperglycemic episodes in this study group was less than what we previously reported from the same city (17%).^[12] The patients in the high-risk group developed much more hyperglycemic episodes than in the low-risk group, but that was not statistically significant (13.5% vs. 0%, $P = 0.14$). No single episode of DKA or HHS occurred in the study group. All hyperglycemic episodes happened in patients treated with insulin (10 on basal-bolus regimen and 1 on premixed insulin).

Despite the increasing volume of medical literature on diabetes and Ramadan fasting, limited data are published on high-risk groups.^[13,14] Although this is the first reported prospective cohort study comparing the high- and low-risk groups, the small number of both the cohorts might have underpowered the study, and further, larger, multicenter studies are needed in the future. Furthermore, the high- and very high-risk categories are heterogeneous groups including patients with different conditions and unmatched baseline characteristics which might have different impacts on fasting outcomes; therefore, the future studies must include patients with selected conditions and matched baseline characteristics.^[15]

CONCLUSIONS

Patients in the high-risk category are significantly more likely to breakfasting during Ramadan than those in the low-risk category. Hypoglycemia is significantly higher in the high-risk group. The rates of severe hyperglycemia, hospitalization, and presumed mortality were not significantly higher in the high-risk group. Being treated with insulin is the most significant risk factor for breakfasting in this study. Risk stratification for all people with diabetes

is of paramount importance before Ramadan fasting is undertaken.

Acknowledgment

The authors would like to acknowledge all medical colleagues and nursing staff for their support during the conduct of this study.

Authors' contributions

All authors contributed to the conception and conduct of the study, data analysis, and drafting and revising of the manuscript. The authors were saddened by the loss of one member of the team (Dr. Abdelwahab Elbarsha) after the completion of this work.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Compliance with ethical principles

The study was conducted according to the Declaration of Helsinki (2013). Approval of the study was granted by the Research Ethics Committee of Benghazi Medical Center, Benghazi, Libya. Participants provided informed verbal consent for their data to be used in the study anonymously.

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