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Fasting during Ramadan and its effects on glycemic control and other metabolic markers among diabetic patients stratified to different risk groups

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ABSTRACT

The objective of this study is to assess the metabolic control of diabetes during Ramadan fasting among different risk groups. This cohort study included 203 diabetic patients attending Prince Abdulaziz Bin Majid Diabetic Center in Madinah, who intended to fast during Ramadan 2014. They were divided into high-risk group (68.47%), low-risk group (23.65%) and very high-risk group (7.88%). Weight, waist circumference (WC), blood pressure (BP), glycosylated hemoglobin (Hb A1c), creatinine and lipid profile were all measured 2 weeks before Ramadan, 4 weeks during the period of the fast and on the week that followed the end of the month. Hypoglycemia was highest in the very high-risk group (42.9%) which consisted of type 1 diabetics. Hb A1c significantly decreased in the high (9.13 ± 1.46% vs 8.75 ± 1.46%), (p=0.014) and very high-risk (9.88 ± 2.00 vs 8.64 ± 1.67), (p = 0.005) groups but increased in the low-risk group (7.0548 ± .93% vs 7.49 ± .99%), (p=0.002). Weight, WC, BP, creatinine, and lipid profile were similar in low- and high-risk patients. The very high-risk group showed significantly increased systolic BP and total cholesterol levels (P= 0.018 and 0.001). In conclusion, fasting Ramadan has different impacts on glycemic control among different risk groups. Hypoglycemia and other unfavorable effects observed among the very high-risk group mandate close monitoring during fasting.

Keywords: Diabetes, fasting, Ramadan, risk groups.

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INTRODUCTION

Many studies have evaluated the metabolic effects of fasting during the month of Ramadan on patients with diabetes, and have found inconsistent results (Akhan et al., 2000; Sadr et al., 2001; Mafauzy et al., 1990; Beshyah, 2009; M'guil et al., 2008). Some reported favorable fasting effects on fasting blood glucose, dyslipidemia and body weight (Al-Shafei, 2014; Azizi, 2010; Ismail et al., 2011; Bagraicik et al., 1994; Beckman et al., 2002). Others reported issues on the safety and efficacy of insulin and oral anti-diabetic drugs during fasting (Beckman et al., 2002; Alghadyan, 1993). Some others reported adverse events with fasting, especially with longer fasting periods (Eshoj et al., 2001; Salti et al., 2004). EPIDIAR study showed that in patients with type 1 diabetes there are a 4.7-fold increase in severe hypoglycemia and a 3-fold increase in severe hyperglycemia with or without ketoacidosis. Same study reported that in patients with type 2 diabetes, there are a 7.5-fold increase in severe hypoglycemia and a 5-fold increase in severe hyperglycemia (Salti et al., 2004). However, most of these studies addressed the different effects of Ramadan fasting irrespective of patient risk categories and, thus, the generalization of their results to all diabetic patients who are going to fast could be limited. The presence of risk factors, their number and severity affect patients response to fasting. The 2010 recommendations for the management of diabetes during Ramadan) included that patients with type 1 (T1DM) or type 2 diabetes (T2DM) who decide to fast Ramadan to be classified according to their risk for adverse events

into 4 risk categories (Al-Arouj et al. 2010). Categorization was based on type of diabetes, history of hypoglycemia, ketosis or hyperosmolar hyperglycemic coma, glycemic control, acute illness, physical labor, pregnancy, chronic dialysis, macrovascular complications, social background, medications, comorbid conditions, and age (Al-Arouj et al., 2010). Risk stratification will help physicians to discuss the decision of fasting the month of Ramadan with the patients and also to guide those who insist to fast even with an increased risk. Safe Ramadan fasting should start with risk stratification for proper individualization, medical assessment, and structured diabetes education. The objective of this cohort study was to assess the effect of Ramadan fasting on the metabolic control of diabetes in different risk groups categorized by the available American Diabetic Association (ADA) 2010 recommendations.

MATERIALS AND METHODS

This cohort study was conducted during Ramadan of the year 2014. Patients were recruited from the "Prince Abdulaziz Bin Majed Diabetic Center" (PABMDC) in Madinah, Saudi Arabia. Patients were interviewed and examined at 2 weeks before the month of Ramadan for recruitment (visit 1) and at approximately 4 weeks after beginning of Ramadan for follow-up assessment (visit 2). Ethical approval for the study was obtained from ethical research board of the PABMDC and verbal informed consents were obtained from all participants. Patients who were eligible for participation were diabetic patients suffering any type of diabetes, for any duration, under any treatment, with any complication or comorbid disease who intended to fast during the upcoming month of Ramadan.

Data collection included all risk variables to ensure proper risk stratification according to the recommendations for risk stratification of T1DM and T2DM patients who fast during Ramadan (Al-Arouj et al., 2010). The very high-risk group included patients with type 1 diabetes, pregnant patients, those under chronic dialysis with poor glycemic control, diabetics with recent ketoacidosis or acute illness, those performing intense physical labor, history of severe or recurrent hypoglycemia, hypoglycemia unawareness, or hyperosmolar hyperglycemic coma within the previous 3 months. The high-risk group included patients living alone, elderly patients with ill health or on drugs that may affect mentation, patients treated with insulin or sulfonylurea, with moderate hyperglycemia, renal insufficiency, advanced macrovascular complications, and those with comorbid conditions. The moderate-risk group were those well-controlled diabetes patients who are treated with short-acting insulin secretagogues; whereas, the low-risk group were the well-controlled diabetes patients who are only treated with lifestyle therapy, metformin, thiazolidinediones, acarbose, and/or incretins with no other co -morbidities.

After recruitment, all patients received individualized education and instructions related to physical activity, meal planning, fluid intake, glucose monitoring. The dosage and timing of medications were advised according to Ramadan-specific diabetes management recommendations. As per guidelines, they were instructed to check their blood glucose level regularly pre-Iftar (breaking fast at sun set), 3 h post-Iftar, pre-Sahor (just before starting the fast) and at any time they developed bothering symptoms during fasting hours. Patients were advised to keep a record of hypoglycemic events and blood sugar testing results that been done at the time of each event to confirm it. Patients were also asked to report admission to a hospital with any acute complications including diabetic ketoacidosis (DKA), hyperosmolar hyperglycemic state or hypoglycemia that if happened, they were advised to break their fast immediately. A hypoglycemic event was defined by low blood sugar (<70 mg/dl) with or without symptoms and a severe hypoglycemic event was defined by blood <40 mg/dl, while hyperglycemia is defined by high blood sugar above 250 mg/dl. Data were collected both before and after Ramadan using one structured pre-coded questionnaire by the patients' usual physician. Clinical assessment of the participants included personal details, diabetes type and duration, complications, coexistent diseases, frequency and type of current treatment. Physical examination was performed for physical signs, blood pressure, and anthropometric data (height, weight, and waist circumference). Laboratory work up included HbA1c, creatinine, and fasting lipid profile. After Ramadan, patients were reassessed for blood pressure, anthropometric measurements, as well as frequency and severity of hypoglycemia and/or hyperglycemia and they were subjected to blood sampling for repeated laboratory work up.

Statistical analysis

Data analysis was done using Statistical Package for Social Sciences (SPSS), version 21.0. All the continuous variables with normal distribution and presented as mean ± SD and variables. Abnormal distribution variables are presented as median. ANOVA test was utilized to find the difference in mean values in the 3 risk groups and nonparametric test (Kruskal Wallis Test) was used for categorical variables. $P<0.05$ was considered statistically significant.

RESULTS

This cohort study included 203 patients (75 males and 128 females), of whom 191 (94.1%) were Saudis. Their median age was 53 years and the median duration of diabetes was 10 years. Overall, 187 (92.12%) were T2DM patients and the remaining 16 (7.88%) were T1D patients. Of all 203 recruited patients, 177 (87.19%) completed the study. The dropout rate was 12.81% (11 did not fast and 15 missed the follow-up period). (12.5%) of patients in the very high risk and (5.75%) of the high risk could not fast, while only 2% in the low risk group did not fast. Categories of risks of patients who insisted on fasting during the month of Ramadan (Figure 1) showed that most patients were in the high-risk group (139 (68.47%)), followed by the low-risk group (48 (23.65%)) and the very high-risk group (16 (7.88%)). No one was in the moderate severity group. Table 1 shows the demographic and biochemical characteristics of the 3 risk groups. The high-risk group included all cardiac patients and the very high-risk group included all T1D patients under basal bolus therapy. Compared with other risk groups, T1D patients were younger (p=0.000), thinner (p=0.000 for BMI and 0.001 for WC), more actively working (p=0.000), and had higher prevalence of smoking (p=0.007), lower prevalence of hypertension (p= 0.029), lower serum levels of triglycerides (p=0.032) and less glycemic control (higher A1C (p=0.000)) (Table 1). Oral

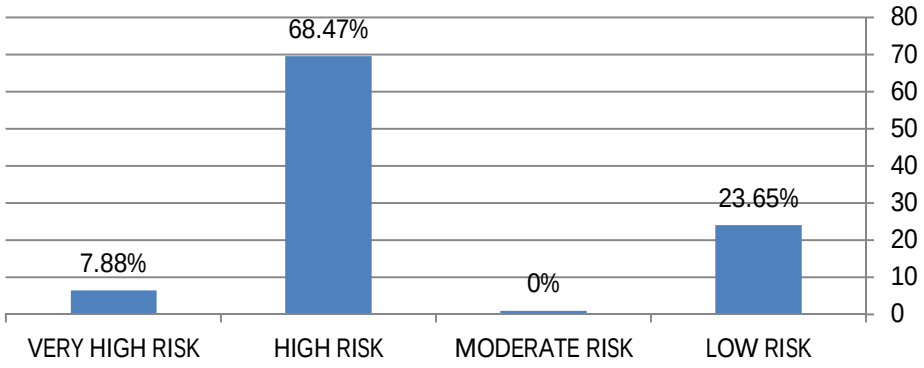

Figure 1. Categories of risks of patients who fasted during Ramadan.

Table 1. The baseline demographic and biochemical characteristics of the 3 risk groups.

Parameter	Low-risk group N = 48	High-risk group N = 139	Very high-risk group N = 16	P
Age: mean ± SD (Years)	52.88 ± 12.76	53.85 ± 10.95	24.20 ± 6.07	0.000*
Duration: mean ± SD (Years)	10.58 ± 8.88	11.81 ± 7.29	6.77 ± 5.17	0.065
Employed: n (%)	6 (12.5%)	18 (12.9%)	3 (18.8%)	0.000*
Smoking: n (%)	2 (4.2%)	7 (5%)	4 (25%)	0.007*
Neuropathy: n (%)	15 (31.3%)	60 (43.2%)	4 (25%)	0.171
Retinopathy: n (%)	7 (14.6%)	35 (25.2%)	2 (12.5%)	0.201
Nephropathy: n (%)	3 (6.3%)	15 (10.8%)	1 (6.3%)	0.589
CAD: n (%)	0 (0%)	16 (11.5%)	0 (0%)	0.019$
PVD: n (%)	0 (0%)	2 (1.4%)	0(0%)	0.630
Foot Ulcers: n (%)	0 (0%)	3 (2.2%)	0(0%)	0.498
HTN: n (%)	23 (47.9%)	81 (58.3%)	4 (25%)	0.029*
Hypothyroidism: n (%)	8 (16.7%)	33 (23.7%)	3 (18.8%)	0.567
OAD: n (%)	100 (100%)	67 (48.2%)	0 (0%)	
Insulin: n (%)	0 (0%)	26 (18.7%)	16 (100%)	0.003*
Both: n (%)	0 (0%)	46 (33.1%)	0 (0%)	
BMI: mean ± SD (kg/m^2)	34.44 ± 7.58	32.10 ± 7.39	23.69 ± 6.77	0.000*
WC: mean ± SD (cm)	108.84 ± 13.32	105.02 ± 13.38	90.82 ± 17.87	0.001*

OAD: Oral anti-diabetic drugs, BMI: Body mass index, WC: Waist circumference, CAD: Coronary artery disease, PVD: Peripheral vascular disease, HTN: Hypertension.
*Significant difference between very high-risk group and other groups.
$ Significant difference between high-risk group and other groups.

hypoglycemic agents constituted the treatment regimen for all low-risk group and for 48.2% of the high-risk group, whereas 33.1%of the high-risk patients were on a combination of oral hypoglycemic agents and insulin. Insulin was the only therapy for all of the very high-risk patients and for 18.7% of the high-risk ones. No patient reported DKA, hyperosmolar hyperglycemic state, or other acute conditions. Overall, hypoglycemia was observed in 26 (14.7%) patients (5 cases (2.8%) were severe). Of the hypoglycemia reported, 4 (8.5%) were low-risk patients, 16 (12.2%) high-risk of these 3 suffered severe hypoglycemia, and 6 (42.9%) very high-risk patients; 2 of them were severe (p=0.002). Hyperglycemia was reported in 3 (6.4%) low-risk patients, 16 (12.2%) high-risk, and 3 (21.4%) very high-risk patients (p=0.501) (Figure 2).

After Ramadan, when testing all patients who fasted during Ramadan we found a significant drop in the mean HbA1c from 8.65 ± 1.67% to 8.44 ± 1.49% (p=0.030). The mean HbA1c significantly dropped from 9.13 ± 1.46% to 8.75 ± 1.46 % (p=0.002) in the high-risk group and from 9.88 ± 2% to 8.64 ± 1.67% (p=0.014) in the very

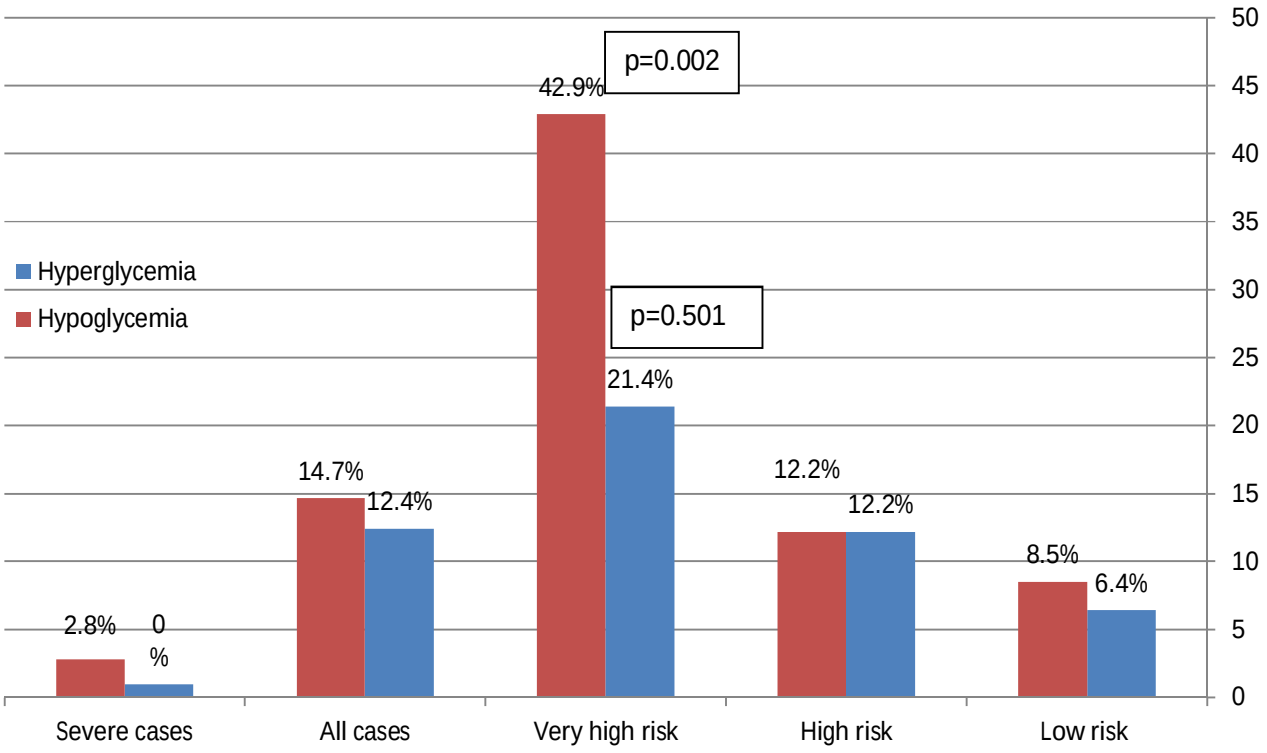

Figure 2. Incidence of hypoglycemia and hyperglycemia in the 3 risk groups during Ramadan fasting.

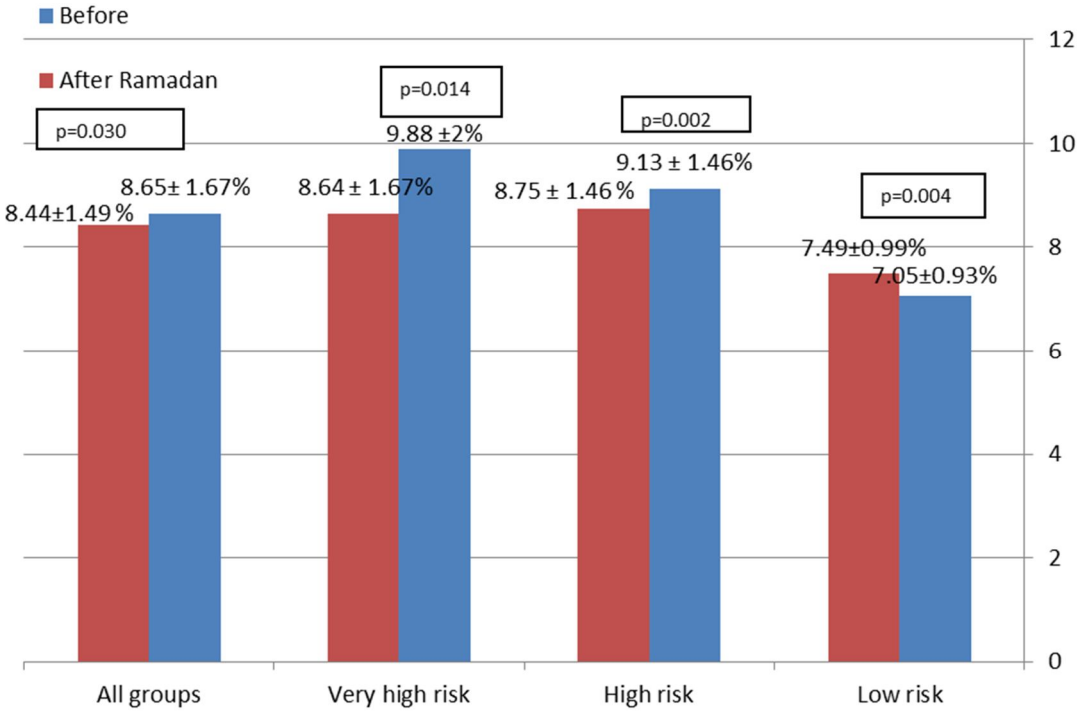

Figure 3. Effect of Ramadan fasting on A1C in different risk groups.

high-risk group. On the contrary, the mean level of HbA1c significantly increased in the low-risk group from 7.05 ± 0.93% to 7.49 ± 0.99% (p=0.004) (Figure 3). The mean weight, WC, diastolic blood pressures, LDL, HDL,

Table 2. Effect of Ramadan fasting on metabolic variables in different risk groups.

Parameter		Low-risk group N = 48	High-risk group N = 139	Very high-risk group N = 16
SBP: mmHg	B	133.88 ±19.83	131.26 ± 18.25	122.00 ± 15.15
	A	139.25 ± 24.17	130.52 ± 21.48	139.00 ± 19.84
	P	0.247	0.843	0.018*
DBP: mmHg	B	72.63 ± 8.57	74.11 ± 9.35	80.60 ± 15.77
	A	71.25 ± 16.29	73.78 ± 12.10	81.40 ± 10.33
	P	0.778	0.881	0.782
WT: Kg	B	83.01 ± 17.79	81.60 ± 19.95	62.62 ± 25.42
	A	84.00 ± 19.69	81.15 ± 20.14	66.62 ± 25.35
	P	0.267	0.201	0.068
WC: cm	B	109.73 ± 12.26	106.41 ± 12.95	93.56 ± 18.78
	A	109.50 ± 12.84	105.08 ± 15.90	91.56 ± 16.27
	P	0.770	0.295	0.431
HbA1c:%	B	7.05 ± 0.93	9.13 ± 1.46	9.88 ±2.00
	A	7.49 ± .99	8.75 ± 1.46	8.64 ± 1.67
	P	0.004*	0.002*	0.014*
TC: mmol/L	B	4.68 ± 1.36	4.66 ± 1.19	4.41 ±0.72
	A	4.72 ± 1.41	4.52 ± 1.10	4.83 ± 0.68
	P	0.742	0.172	0.001*
TG: mmol/L	B	1.75 ± 1.21	1.81 ± 1.16	0.88 ± 0.51
	A	1.72 ± 1.27	1.70 ± 1.03	1.13 ±0.43
	P	0.876	0.295	0.063
LDL: mmol/L	B	2.69 ± 1.19	2.65 ± 0.94	2.47 ± 0.79
	A	2.69 ± 1.04	2.54 ± 0.90	2.80 ± 0.55
	P	0.969	0.232	0.116
HDL: mmol/L	B	1.21 ± 0.33	1.18 ± 0.36	1.50 ± 0.40
	A	1.22 ± 0.45	1.20 ± 0.42	1.54 ± 0.44
	P	0.907	0.592	0.734
Creatinine: mmol/L	B	80.59 ± 18.70	85.50 ± 29.06	75.13 ± 31.04
	A	82.28 ± 20.18	84.03 ± 27.71	75.63 ± 24.11
	P	0.340	0.403	0.886

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, WT: Weight, WC: Waist circumference, HbA1C: glycosylated hemoglobin, TC: total cholesterol, TG: Triglycerides, LDL: Low density lipoprotein, HDL: High density lipoprotein, B: Before Ramadan, A: After Ramadan, P: Significance.
*Significant difference of variable levels before and after Ramadan fasting.

triglyceride and creatinine levels were not significantly different (p>0.05) before and after Ramadan in the 3 risk groups, as shown in Table 2. The very high-risk group showed significant changes in some other variables other than HbA1c, including an increase in systolic blood pressure from 122.00 ± 15.15 to 139.00 ± 19.84 mmHg (p=0.018) and an elevation of serum level of total cholesterol from 4.41 ±0.72 to 4.83 ± 0.68 mmol/L (p= 0.001) (Table 2).

DISCUSSION

This cohort study classified diabetic patients who wish to observe Ramadan fasting into high-risk group (69.5%), low-risk group (24%) and very high-risk group (6.5%). The number of patients who could not fast was higher in both the very high-risk (12.5%) and the high-risk (5.8%) groups, no one was in the moderate severity group. The very high-risk group included all T1DM patients and the

high-risk group included all cardiac patients. Different risk groups showed significant differences in their ability to fast. During fasting, hypoglycemia was reported in 14.7% (severe in 2.8%) of cases and hyperglycemia was reported in 12.4% with no reported acute complications or hospital admission for any reason. In this study, fasting during Ramadan was possible for the very high-risk group (T1DM), as 87.5% of them insisted and continued to fast despite the reported high frequencies of both hypoglycemia (42.9%) and hyperglycemia (21.4%). It is well recognized that it is safe for adult patients with T1DM and T2DM to fast during Ramadan if there were proper education, appropriate adjustment of the drug regimen, diet control, and suitable daily activity, (Ismail et al, 2011; EPIDIAR study group, 2004; Ghouri et al., 2012; Salti et al., 2004). In one study (Benaji et al., 2006), only 10% of T1DM patients developed hypoglycemia during fasting; however, hypoglycemia developed in 33.3% of patients who broke their fast. In another study hypoglycemia resulted in breaking the fast in at least one occasion in 61.5% of T1DM patients (Beshyah et al., 2007). There was a significant drop in the HbA1C of the very high-risk group (from 9.88 ± 2% to 8.64 ± 1.67% (p=0.014)) which could explain the increased frequency of hypoglycemia among them. The reasons for the higher rate of hypoglycemia in our patients (42.9%) may be due to longer hours of fasting in Saudi Arabia and the larger percentage of T1DM patients who continue to fast. With fasting, in our cohort, there was no weight change in T1DM after the end of Ramadan; whereas one study found a decreased patients weight (Benaji et al., 2006) and another found an increase in weight with fasting (Beshyah et al., 2007), which could be attributed to differences between different nations in their dietary and physical activity during Ramadan fasting. After all, it is still necessary to consider not to fast Ramadan in T1DM patients if they fall under the very high-risk category particularly if they are poorly controlled, with limited access to emergency medical care, have hypoglycemic unawareness, unstable glycemic control, recurrent hospitalizations for diabetes, or if they will not monitor their blood glucose levels several times daily. The evidence behind the very high-risk stratification of T1DM during fasting is still lacking as most available studies (even this study) included small number or excluded adolescents or those with comorbid diseases (Zabeen et al., 2014; Al-Khawari et al., 2010; Hui et al., 2010; Karamat et al., 2010). One review (Hui and Devendra, 2010) addressed the managing of T1DM patients who wish to fast during the month of Ramadan and concluded that these patients should follow specific recommendations and be closely monitored by their physician in order to achieve safe fasting with minimal complications.

After the end of the month of Ramadan, glycemic control was the single variable that showed significant changes in the 3 risk groups who fasted. There was a significant drop in the mean HbA1c (from 8.65 ± 1.67% to 8.44 ± 1.49% (p=0.030)) in all patients. These results are consistent with some (Beckman et al., 2002; No authors listed, 1998; Kobeissy et al., 2008) but not all the studies, some of which, in contrast, showed no change in the serum HbA1c values (Sulimani et al., 1991; Yarahmadi et al., 2003; Gaaloul et al., 1999). The mean level of HbA1c significantly decreased in both the high- and very high-risk groups but significantly increased in the low-risk group (from 7.05 ± 0.93% to 7.49 ± 0.99%) (p=0.004). Traditionally, carbohydrate-rich foods and excess intake of sugary fluids consumed during non-fasting hours may represent the risk of hyperglycemia in the low-risk group as they were receiving anti-diabetic drugs with a limited ability to lower their postprandial blood sugar.

After Ramadan, weight and WC were unchanged in the 3 risk groups. Weight was also found to be unchanged by some researchers (Beckman et al., 2002; Sari et al., 2004; Chamakhi et al., 1991) but not others (Ismail et al., 2011; Kobeissy et al., 2008; Sulimani et al., 1991). Some authors explained the absent weight changes by the increase in fat intake in compensation for the decrease in carbohydrate intake during Ramadan (Sari et al., 2004). Another explanation is the positive effects of dietary and life style changes as advised during Ramadan fasting (Chamakhi et al., 1991). In concordance with absent weight changes, the lipid profile was also stable after Ramadan fasting except in the very high-risk group, where the total cholesterol significantly increased (from 4.41 ± 0.72 to 4.83 ± 0.68 mmol/L) (P= 0.001). Studies have shown inconsistent results with regard to the effect of Ramadan intermittent fasting on lipid profile, as some found an unaltered profile (Beckman et al., 2002; Ahmedani et al., 2014; Khatib and Shafagoj, 2004), whereas others reported improved lipid profile with a decrease mainly in triglycerides (Gaaloul et al., 1999) and an increase in high density lipoprotein (Gaaloul et al., 1999; Aksungar et al., 2005). Detrimental effect with an increase in both total cholesterol and low density lipoprotein was reported by others (Sulimani et al., 1991). M'guil et al. (2008) studied well controlled diabetes patients that we could consider them as low-risk group and found non-significant fluctuations in their lipid profile, creatinine, urea, uric acid, total protein, bilirubin, and electrolytes after the month of Ramadan. Another study addressed the lipid profile changes in 11 insulin-treated patients during Ramadan, and similarly to our results, they found an increase in total cholesterol, and a fall in HbA1c (Hui and Devendra, 2010). Absence of the moderate-risk group in our cohort could reflect the difficult criteria in selecting this group in particular

CONCLUSION AND RECOMMENDATIONS

Fasting during Ramadan has significant and different effects on glycemic control among different risk groups.

Overall, glycemic control tends to improve in all patients except the low-risk group. In the very high-risk group (T1DM patients), fasting was possible with high frequencies of non-severe hypoglycemia and hyperglycemia, but not DKA, although they may have unfavorable effects on blood pressure and lipid profile. Thus, the inclusion of any T1DM patient within the very high-risk group may not be appropriate. Although results showed that risk stratification was appropriate in predicting the different outcome of some risk groups, the criteria for inclusion of each group might need more assessment for further modification, probably through larger-scale studies.

Strengths and limitations

To the best of our knowledge, this study was the first study that addressed the risk stratification of the diabetic cohort who wished to fast during Ramadan according to recent recommendations. The dropout rate (12.81%) in the study was not high. The main limitations of this study are the absence of non-fasting control group and the small size of the very high-risk group. The change in blood pressure measurements based on a single reading 6 weeks after Ramadan may not reflect the effects of fasting. Moreover, the "very high risk" group is solely T1DM which limits comparison of different risk categories of the same disease. In the view of absence of risk stratification in almost all previous studies, it was difficult to compare between our results and others' findings. One more limitation of generalization is that this study was performed when Ramadan was in a hot humid atmosphere that could affect every metabolic parameter and could make the comparison with other studies more difficult.

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Conflict of interest

Authors disclose that they have no conflict of interest.

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