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Safety of Fasting in Patients with Type 1 Diabetes during Ramadan: A Prospective Study from Pakistan

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Authors' contributions

This work was carried out in collaboration between all authors. Author MYA gave Concept and designed the study, interpreted the data, edited and reviewed the manuscript. Author SFDA gave concept and designed the study, interpreted the data, wrote and reviewed the manuscript. Authors AF, MSU, SN and AB edited and reviewed the manuscript. All authors read and approved the final manuscript.

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ABSTRACT

Aims: To observe safety of fasting in patients with type 1 diabetes during Ramadan.
Methods: A prospective, case control study was conducted in the Out-patient department of Baqai Institute of Diabetology and Endocrinology from June to September 2013. The study was carried out in two phases; Pre-Ramadan recruitment phase (Visit A) and Post-Ramadan follow-up phase (Visit B) of the same patients. In visit A, Ramadan-specific diabetes education was delivered by health care providers in group session and educational material provided to each patient.
Results: Sixty two patients with type 1 diabetes (42 in fasting and 20 in non-fasting group) participated in the study. No significant change ($p > 0.05$) observed in weight and HbA1c of fasting and non-fasting groups before and after Ramadan. During Ramadan, out of 1380 blood glucose

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readings in fasting group, there were 98 (7.1%) and 570 (41.3%) episodes of hypoglycemia and hyperglycemia respectively. None of the patients developed diabetic ketoacidosis and none required hospitalization. No significant difference ($p > 0.05$) observed in the frequency of hypoglycemia while hyperglycemia increased ($p < 0.05$) when glycemic status during Ramadan was compared with Pre-Ramadan. No significant difference ($p > 0.05$) observed in the frequency of hypoglycemia and hyperglycemia when Ramadan was compared with Post-Ramadan.

Conclusion: We observed that majority of patients with type 1 diabetes did not have serious acute complications of diabetes during Ramadan. Safety of fasting can be ensured in patients with type 1 diabetes with Ramadan-specific diabetes education and medical supervision.

Keywords: Ramadan; type 1 diabetes; fasting.

1. INTRODUCTION

Fasting in the month of Ramadan is one of the five pillars of Islam [1]. Worldwide, around 50 million Muslims with diabetes hold fast during Ramadan each year [2]. In Ramadan, all healthy adult Muslims are obligated to fast. However, if health of the individual is adversely affected by fasting, the religion Islam exempts that individual from holding fast for as many days as necessary [3].

Many patients with type 1 diabetes insist on fasting during Ramadan because they feel spiritually and psychologically inclined to fast like other Muslims [4]. Their insistence on fasting could also be a reaction against the feeling that as a result of their disease, they are physiologically different from other members of the community [5]. Some patients with type 1 diabetes even fast against the advice of their physicians and may develop complications [1,6].

The population based study, Epidemiology of Diabetes and Ramadan (EPIDIAR), conducted in 13 Islamic countries, showed that 43% of patients with type 1 diabetes reported fasting. During Ramadan, the frequency of at least one episode of severe hypoglycemia requiring hospitalization was 9%, while frequency of at least one episode of severe hyperglycemia with / without ketoacidosis requiring hospitalization was 13% in patients with type 1 diabetes [1]. As a result of these observations fasting in patients with type 1 diabetes was regarded as high risk [7]. However, current evidence suggests that patients with type 1 diabetes can fast during Ramadan under the supervision of health care providers especially, if their glycemic control is good and they do self-monitoring of blood glucose [8-10].

Recommendations and suggestions regarding fasting in patients with type 1 diabetes from expert physicians depend on their personal experiences and there are not many prospective studies. Despite the observation that many patients with type 1 diabetes fast during Ramadan particularly in Muslim countries, the data on safety of fasting in patients with type 1 diabetes are sparse.

Hence a study was designed to observe the safety of fasting in patients with type 1 diabetes during Ramadan.

2. METHODOLOGY

A prospective, case control study was conducted in the Out-patient department (OPD) of Baqai Institute of Diabetology and Endocrinology (BIDE) from June to September 2013 (Hijri year 1434). During Ramadan the average fasting period in Pakistan was around 15 hours per day. Ethical approval for the study was obtained from the Institutional Review Board (IRB) of BIDE. The study was carried out in two phases; a Pre-Ramadan recruitment phase (Visit A) and a Post-Ramadan follow-up phase (Visit B) of the same patients. A diabetes educator involved in the care of patients with type 1 diabetes was assigned the task to enroll patients for the study after obtaining informed consent.

2.1 Inclusion Criteria

Patients with type 1 diabetes (aged ≥ 15 years) who showed intention to fast in Ramadan were included in the fasting group. Patients with type 1 diabetes unwilling to fast were included in the non-fasting group.

2.2 Exclusion Criteria

Patients with type 2 diabetes, patients with type 1 diabetes with serious complications, patients with brittle type 1 diabetes, pregnant females, newly diagnosed patients (< 3 months), hospitalized individuals and patients with type 1 diabetes having hypoglycemia unawareness were excluded from the study.

2.3 Pre-Ramadan Phase (Visit A)

Patients with type 1 diabetes were recruited in the study one month before Ramadan, 2013. They were also assessed for their physical well-being and metabolic control at the time of recruitment.

2.4 Data Collection

A face-to-face, standardized, questionnaire-based interview was conducted by the diabetes educator. Detailed history was taken from the patients. Information collected included socio-demographic and anthropometric data, duration of the disease, comorbidities, frequency and type of insulin, diet and physical activity level including type of exercise and routine blood glucose monitoring practices. Glycated hemoglobin (HbA1c) test was done of the patients with type 1 diabetes in the fasting and non-fasting groups.

Patients in the fasting and non-fasting groups were provided glucometers and strips and advised to start self-monitoring their blood glucose (SMBG) at home from one month before Ramadan according to their usual routine [at least twice a day at different specified times including Pre-Dawn (before Sehar), Post-Dawn (after Sehar), Mid-day, Pre-Dusk (before Iftar) and Post-Dusk (after Iftar)] and in addition, when they experienced any hypo- or hyperglycemia symptoms and chart their blood glucose readings in a notebook especially designed for the study. They were also told to contact diabetes educator immediately for assistance on a 24-h emergency cell phone helpline service.

2.5 Group Session

Patients in the fasting group were advised to attend group education session fifteen days before Ramadan. The group session was conducted by physicians, diabetes educator and dietician. The session lasted for 2 hours. In the education session patients were educated regarding hypo and hyperglycemia symptoms, self-monitoring of blood glucose, especially if they develop symptoms, insulin dosage and timing alteration, diet and fluid intake during Ramadan and when to break the fast. Patients were also encouraged to continue their routine physical activities during Ramadan and advised to refrain from doing heavy physical activity during fasting. Patients were also provided educational material regarding diet and exercise during Ramadan.

Adjustments were also made in the insulin dosage and timing. The decision for altering the insulin regimen was at the physician's discretion depending on the glycemic control of the individual patients. Patients were also advised to note down their blood glucose readings during Ramadan and up to one month Post-Ramadan.

2.6 Post-Ramadan Follow-up Phase (Visit B)

The second phase (Visit B) was conducted one month after the end of Ramadan, 2013. In visit B second interview was conducted of patients in the fasting and non-fasting groups. Information collected included anthropometric data, number of days of fasting during Ramadan, development of symptoms of hypoglycemia and hyperglycemia and if developed, the frequency of the symptoms and the measures taken, hospital admission for any medical reason, frequency of blood glucose monitoring during Ramadan, frequency and type of insulin during Ramadan and physical activity level including type of exercise during Ramadan. Pre-Ramadan, during Ramadan and Post-Ramadan SMBG and dietary records were also collected and HbA1c was done of the fasting and non-fasting groups.

2.7 Hypoglycemia

Hypoglycemia was defined as blood glucose level < 3.9 mmol/l [11].

2.8 Hyperglycemia

Hyperglycemia was defined as blood glucose level > 11.1 mmol/l [11].

2.9 Statistical Analysis

Data analysis was conducted on Statistical Package for Social Sciences (SPSS), version 13.0. All the continuous variables, i.e. age, duration of diabetes, weight, height, body mass index (BMI), systolic and diastolic blood pressure, fasting blood sugar, HbA1c, presented as Mean ± SD. Categorical variables, such as gender and treatment modality presented as number and percentage. A paired t-test was utilized to find the difference in mean values and chi square used for categorical variables. $P < 0.05$ was considered as statistically significant.

3. RESULTS

A total of 62 patients with type 1 diabetes (42 in the fasting group and 20 in the non-fasting

group) participated in the study. The mean days of fasts in the fasting group were 20.48 ± 7.22 days. Table 1 shows baseline demographic and biochemical characteristics of the studied population. Mean age of the patients in the fasting group was 19.83 ± 4.49 years whereas; in the non-fasting group patients were younger with the mean age of 18.75 ± 4.16 years. Mean duration of diabetes was 7.11 ± 5.50 and 6.72 ± 4.52 years in the fasting and non-fasting groups respectively. Majority of the patients in the fasting and non-fasting groups were on regular and NPH insulin.

No statistically significant difference ($p > 0.05$) was observed in weight, body mass index and systolic blood pressure of the fasting and non-fasting groups before and after Ramadan. However, diastolic blood pressure showed a significant decrease from 74.98 ± 4.93 mmHg before Ramadan to 71.93 ± 6.70 mmHg after Ramadan ($p = 0.022$) in the fasting group as shown in Table 2.

Pre-Ramadan HbA1c of the patients in the fasting group was 9.10 ± 2.29% which decreased to 8.98 ± 2.17% Post-Ramadan ($p = 0.466$). In the non-fasting group, Pre-Ramadan and Post-Ramadan HbA1c was 9.24 ± 2.05 and 9.13 ± 2.04% respectively ($p = 0.711$).

During Ramadan, total of 1380 and 393 blood glucose readings were obtained in the fasting and non-fasting groups respectively. There were 98 (7.1%) episodes of hypoglycemia (< 3.9 mmol/l) in the fasting group and 25 (6.4%) episodes in the non-fasting group ($p = 0.610$). However, there were 570 (41.3%) episodes of hyperglycemia (> 11.1 mmol/l) in the fasting group and 108 (27.5%) episodes in the non-fasting group; the difference was statistically significant ($p < 0.001$).

The frequency of symptoms of hypoglycemia and hyperglycemia during Ramadan in the fasting group is shown in Table 3. At least one episode of symptoms of hypoglycemia was observed in 26 (61.90%) patients with type 1 diabetes. On the development of symptoms of hypoglycemia blood glucose level was checked by all the patients and fasting was discontinued by 6 (23.07%) patients. Similarly, at least one episode of symptoms of hyperglycemia was felt by 34 (80.95%) patients during Ramadan. Blood glucose level was checked by 26 (76.47%) patients and fasting was discontinued by 2 (5.88%) patients when they felt symptoms of hyperglycemia. None of the patients with type 1 diabetes developed diabetic ketoacidosis and none required hospitalization when they developed either symptoms of hypoglycemia or hyperglycemia. None of the patients developed severe hypoglycemia (requiring third party assistance), none developed diabetic ketoacidosis or required hospitalization when they developed either symptoms of hypoglycemia or hyperglycemia.

Table 1. Baseline demographic and biochemical characteristics of the studied population

	Fasting group	Non-fasting group
n	42 (67.7%)	20 (32.3%)
Gender		
Male	20 (47.61%)	11 (55%)
Female	22 (52.38%)	9 (45%)
Age (years)	19.83 ± 4.49	18.75 ± 4.16
Duration of diabetes (years)	7.11 ± 5.50	6.72 ± 4.52
Weight (kg)	54.05 ± 10.49	49.80 ± 10.71
Height (cm)	160.15 ± 7.84	157.50 ± 8.91
Body mass index (kg/m²)	21.00 ± 3.49	19.96 ± 3.25
Systolic blood pressure (mmHg)	110.25 ± 12.90	106.50 ± 9.88
Diastolic blood pressure (mmHg)	74.98 ± 4.93	74.50 ± 6.04
Fasting blood sugar (mmol/l)	8.33 ± 4.7	9.47 ± 5.86
Random blood sugar (mmol/l)	11.89 ± 5.43	12.13 ± 7.06
HbA1c (mmol/mol)	76 ± 2	77 ± 1
HbA1c (%)	9.10 ± 2.29	9.24 ± 2.05
Type of insulin		
Regular	36 (46.15%)	18 (46.15%)
NPH	37 (47.43%)	18 (46.15%)
Others	5 (6.41%)	3 (7.69%)

Data presented as Mean ± SD; n (%)

Table 2. Changes in weight, body mass index and blood pressure before and after Ramadan (n=62)

	Fasting group			Non-fasting group		
	Before Ramadan	After Ramadan	p-value	Before Ramadan	After Ramadan	p-value
Weight (kg)	54.05±10.49	54.56±11.22	0.833	49.80±10. 71	49.97±10.80	0.959
Body mass index (kg/m²)	21.0 ±3.49	21.31±3.71	0.706	19.96±3.25	20.20±2.97	0 .802
Systolic blood pressure(mmHg)	110.25±12.90	113.21±14.72	0.336	106.50±9.88	106.00±11.42	0.883
Diastolic blood pressure(mmHg)	74.98±4.93	71.93±6.70	0.022	74.50±6.04	71.50±5.87	0 .120

Data presented as Mean ± SD
P < 0.05 considered statistically significant

Table 3. Frequency of symptoms of hypoglycemia and hyperglycemia during Ramadan in the fasting group (n=42)

	Fasting group
Symptoms of hypoglycemia (on at least one occasion)	
No	16(38.09%)
Yes	26(61.90%)
Checked blood glucose level if developed symptoms of hypoglycemia	
No	0(0.00%)
Yes	26(100%)
If developed symptoms of hypoglycemia	
Continued fast	20(76.92%)
Discontinued fast	6(23.07%)
Symptoms of hyperglycemia (on at least one occasion)	
No	8(19.04%)
Yes	34(80.95%)
Checked blood glucose level if developed symptoms of hyperglycemia	
No	8(23.52%)
Yes	26(76.47%)
If developed symptoms of hyperglycemia	
Continued fast	32(94.11%)
Discontinued fast	2 (5.88%)

Data presented as n (%)

In the fasting group, the highest frequency of hypoglycemic episodes (< 3.9 mmol/l) were seen Post-Dawn (after Sehar), while the highest frequency of hyperglycemic episodes (> 11.1 mmol/l) were observed Pre-Dawn (before Sehar).

Fig. 1 shows the week-wise hypoglycemic and hyperglycemic episodes in fasting group during Ramadan. Hypoglycemic episodes showed a continuous downward trend from week 1 to week 4. The highest number of hyperglycemic episodes occurred in week 2 which decreased in the subsequent weeks.

Glycemic status in the fasting group during Ramadan was compared with Pre-Ramadan and Post-Ramadan as shown in Fig. 2. A total of 860, 1380 and 568 blood glucose readings were obtained Pre, during and Post-Ramadan respectively. No significant change ($p > 0.05$) was observed in the frequency of hypoglycemia when glycemic status during Ramadan was compared with Pre-Ramadan. However, the frequency of hyperglycemia increased significantly from 33.37% Pre-Ramadan to 41.30% during Ramadan ($p < 0.05$). No statistically significant difference ($p > 0.05$) was observed in the frequency of hypoglycemia and hyperglycemia when glycemic status during Ramadan was compared with Post-Ramadan.

4. DISCUSSION

In this prospective study we observed that majority of the patients with type 1 diabetes in the fasting group did not have any serious acute complications of diabetes during Ramadan. None of the patients developed diabetic ketoacidosis and none required hospitalization. No significant difference was observed in the frequency of

hypoglycemia, while hyperglycemia increased when glycemic status during Ramadan was compared with Pre-Ramadan. No significant change was noted in the frequency of hypoglycemia and hyperglycemia when Ramadan was compared with Post-Ramadan.

In the present study, no significant change was observed in weight and body mass index of patients with type 1 diabetes before and after Ramadan, similar to the findings of other studies [4,8,12].

Studies have suggested that mean HbA1c of patients with type 1 diabetes does not show a significant change before and after Ramadan [4,8]. Similar findings were noted in the present study.

In the study systolic blood pressure did not change significantly in the fasting and non-fasting groups similar to our previous study [12]. Interestingly, diastolic blood pressure showed significant decrease in the fasting group. Whether fasting during the month of Ramadan

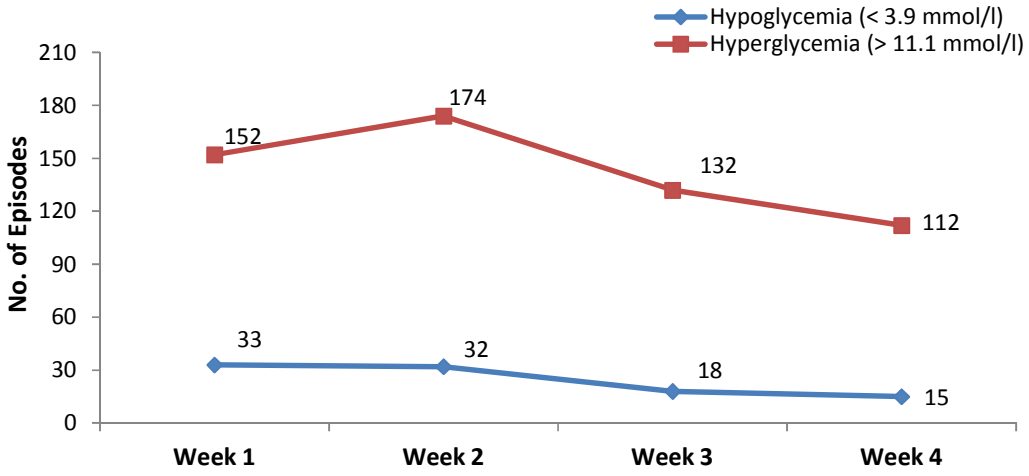

Fig. 1. Week-wise hypoglycemic and hyperglycemic episodes in fasting group during Ramadan (n=42)

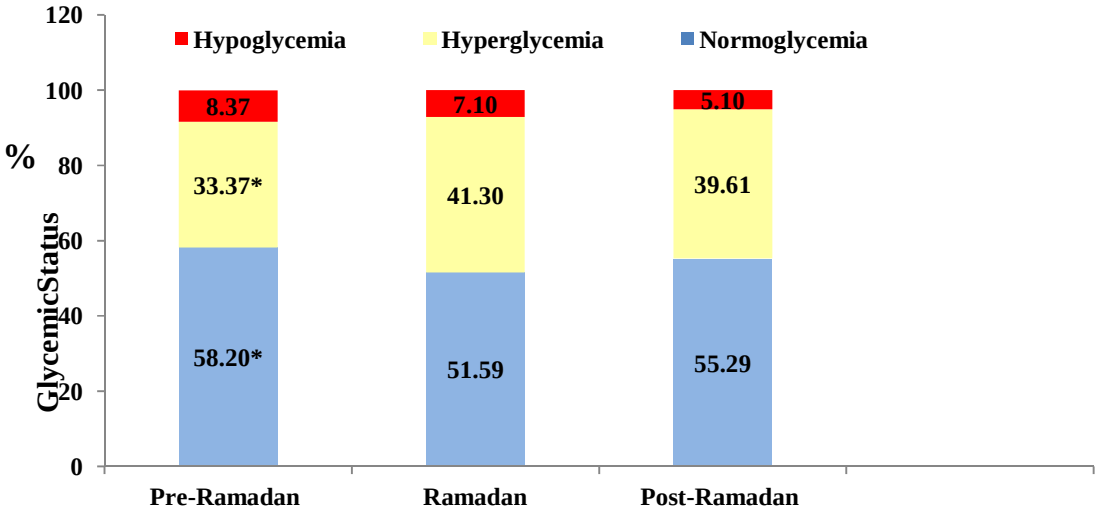

Fig. 2. Comparison of glycemic status during Ramadan with Pre and Post Ramadan in the fasting group (n=42)

**P-value (< 0.05) calculated between Ramadan and Pre-Ramadan; Ramadan and Post-Ramadan*

results in improvement of diastolic blood pressure, needs to be investigated in further studies. Blood glucose monitoring during Ramadan is essential for patients with diabetes who intend to hold fast during Ramadan [13]. In the study, majority of the patients followed the advice and monitored their blood glucose when they felt symptoms of hypoglycemia or hyperglycemia during fasting. Frequent blood glucose monitoring during Ramadan may have enabled our patients to prevent serious acute complications of diabetes during Ramadan.

In this study patients were recommended to immediately discontinue the fast at blood glucose reading of < 3.3 mmol/l [60 mg/dl] because their blood glucose may fall further if treatment is delayed. Patients with type 1 diabetes were also advised to break the fast if blood glucose reaches < 3.9 mmol/l [70 mg/dl] with in the first few hours of starting the fast [13]. Not all patients followed the advice of the breaking the fast in our study may be because Muslims are generally reluctant to break the fast even if there are serious health concerns [14]. This issue needs to be addressed more specifically in Ramadan-specific patient education to ensure safe fasting in patients with diabetes during Ramadan. For patients with diabetes, Pre-Ramadan input from religious scholars and imams of the mosques should also be sought to emphasize on the patients that breaking the fast on the development of serious acute complications is not a sin and they can compensate by holding fast on other days.

In the present study the highest frequency of hypoglycemic episodes in the fasting group were observed Post-Dawn (after Sehar). On further inquiring it was revealed that these patients either did not take proper food at Sehar i.e. before the start of fast or because of higher blood glucose level Pre-Dawn (before Sehar) took extra insulin without increasing their food intake. Similarly, the highest frequency of hyperglycemic episodes occurred Pre-Dawn (before Sehar) may be because of excessive food intake during non-fasting hours. Hence, patients with type 1 diabetes should be advised not to fast without taking food Pre-Dawn (before Sehar).

The study showed that the frequency of hypoglycemia and hyperglycemia decreased over 4 weeks in the fasting group showing overall improvement in glycemic control during Ramadan, similar findings were observed in another study [11].

Usually, patients with type 1 diabetes have an increased risk of hypoglycemia during Ramadan [7]. However, in this study there was no significant difference in the frequency of hypoglycemic episodes in the fasting and non-fasting groups during Ramadan. Moreover, in the fasting group there was no significant change in the frequency of hypoglycemic episodes Pre, during and Post Ramadan. It was may be due to Pre-Ramadan patient education, dietary counseling, adjustment in insulin dosage and close follow up.

During Ramadan the frequency of hyperglycemic episodes increased in the fasting group compared to non-fasting group. In the fasting group the frequency of hyperglycemic episodes also increased during Ramadan compared to Pre-Ramadan. The reason could be excessive consumption of food, especially at Iftar meal. Our previous study suggested that patients with diabetes should spread their food intake in Ramadan into four meals i.e. Pre-Dawn (before Sehar), Post-Dusk (Iftar), Dinner and Bedtime and energy requirements should be maintained from other macronutrients to ensure normoglycemia during Ramadan [15].

The findings of our study suggest that all patients who intend to hold fast should undergo Pre-Ramadan medical assessment and attend a structured education program to undertake the fast as safely as possible.

The limitation of the study was small sample size the study participants were relatively young with short duration of diabetes and poor glycemic control, also people with hypoglycemia unawareness were excluded from the study; hence study population may not represent the entire population with type 1 diabetes who hold fast during the month of Ramadan. The major strengths were; regular follow-up, provision of twenty-four-hour helpline service and substantial blood glucose readings Pre, during and Post Ramadan.

5. CONCLUSION

In this prospective study we observed that majority of the patients with type 1 diabetes did not have serious acute complications of diabetes during Ramadan. Overall glycemic control during Ramadan was not significantly different compared to Pre and Post Ramadan. Not all have similar risk during Ramadan; hence care of patients with type 1 diabetes should be individualized. Safety of fasting can be ensured

in patients with type 1 diabetes with Ramadan-specific diabetes education and medical supervision.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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