

## DAR-GRACE: Diabetes and Ramadan: glycaemic control, physician counselling and patient practices –experience from a tertiary care hospital in Pakistan

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### Abstract

**Objective:** To identify patient practices and knowledge pertaining to Ramadan fasting and to see whether physicians were providing adequate counselling and adjusting medications accordingly.

**Methods:** The cross-sectional study was conducted at the Pakistan Institute of Medical Sciences, Islamabad, Pakistan, from June to August 2018, and comprised diabetic patients who fasted during Ramadan. A questionnaire was designed to assess patients' knowledge, risk category, pre-Ramadan counselling, medication adjustment, lifestyle changes, pre- and post-Ramadan glycated haemoglobin levels, and complications during Ramadan. Data was analysed using SPSS 23.

**Results:** Out of 272 diabetics, 176(64.7%) were females. Mean number of fasts kept were  $22 \pm 10.61$ . Pre-Ramadan 120(44.1%) patients consulted their physicians and 105(87.5%) of them received relevant counselling. Medications were adjusted in only 30 (25%) such cases. Overall, 41 (15.1%) patients were in the high-risk category, while 109(40.1%) and 122(44.9%) were in the moderate and low-risk categories. During the month, 17(6.25%) were hospitalised due to diabetes-related complications. Glycated haemoglobin levels fell significantly ( $p < 0.0001$ ).

**Conclusion:** Anomalous patient behaviours and suboptimal physician practices were noticed.

**Keywords:** Diabetes; Ramadan; Pakistan.

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### Introduction

Fasting during the holy month of Ramadan is one of the five pillars of Islam and is obligatory for all healthy Muslims. Although exemptions exist for the elderly, the infirm, those with serious medical conditions and the pregnant and lactating women, religious sentiments and fervour during Ramadan are high and a majority of individuals choose to fast often against medical advice. During this time, the observers abstain not only from food and drink, but also from smoking, intercourse and oral as well as injectable medications.

A survey encompassing 39 countries including over 38,000 Muslims observed that a median of 93% fasted during Ramadan.<sup>1</sup> The Muslim population of the world is estimated to be 1.8 billion<sup>2</sup> and with each passing year more and more Muslims are fasting around the world.

The Epidemiology of Diabetes and Ramadan (EPIDIAR) study performed in 2001 found that 42.8% of patients with type 1 diabetes mellitus (T1DM) and 78.7% of those with T2DM fasted for at least 15 days during Ramadan.<sup>3</sup> The recent CREED study conducted in 2010 reported that 94.2% of the enrolled type 2 diabetics fasted in Ramadan.<sup>4</sup> Several studies have shown that there is a poor understanding of the physiological effects of fasting amongst the physicians, leading to suboptimal advice being given to the patients.<sup>5</sup>

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The number of patients who reach out to their healthcare providers to seek guidance for Ramadan is also low.<sup>6</sup> This highlights the importance of knowing the physiological impact of Ramadan fasting and the changes required in lifestyle and medication to make it a safe experience for Muslims around the world. During Ramadan fasting, physiological changes affect both the endocrine and homeostatic mechanisms. This is further compounded by the effects of medications so that complications such as hyperglycaemia and hypoglycaemia can both occur.<sup>7</sup> Additionally, there are changes in the timings of the meals and the patterns of sleep, both of which can affect an individual's metabolic state.

Pakistan has one of the highest populations of patients living with diabetes in the world.<sup>8</sup> It is imperative to understand patient factors, physician practices and the epidemiology of Ramadan fasting. There is currently a dearth of scientific data in this sphere. The current study was planned to look into the epidemiology of Ramadan fasting in patients with diabetes, identify pitfalls in the management, identify whether the patients were adequately counselled about fasting, if their medications were changed accordingly and recognition of complications as a result of fasting.

### Subjects and Methods

The cross-sectional study was conducted at the Pakistan Institute of Medical Sciences (PIMS), Islamabad, Pakistan, from June to August 2018, and comprised subjects aged

>20 years with diabetes diagnosed on the basis of American Diabetes Association (ADA) criteria.<sup>9</sup> After approval from the institutional ethics review committee, Rao Online sample size calculator<sup>10</sup> was used taking prevalence of 78.7% patients with diabetes who fasted during Ramadan<sup>3</sup> with 95% confidence interval (CI) and a margin of error 5%. Using consecutive sampling technique the sample was raised from among patients with diabetes who fasted during Ramadan. Those excluded were patients who refused to give consent, had communication barrier or hearing disability.

After taking informed consent from the subjects, data was collected using a pre-designed questionnaire which was filled out by volunteer doctors who were trained before the start of the study regarding the guidelines pertaining to Diabetes and Ramadan by the International Diabetes Federation 2016.<sup>11</sup> Demographic data, such as age, gender, education, socioeconomic status, the type and duration of diabetes and the number of fasts kept, was recorded. Complications such as retinopathy was assessed using fundoscopy, neuropathy using a monofilament examination, nephropathy using urine for microalbuminuria, urine routine examination and renal function tests. The macrovascular complications, such as diabetic foot, ischaemic heart disease, cerebrovascular accident, and peripheral vascular disease were assessed from the patient's records. The pre-Ramadan and post Ramadan glycated haemoglobin (HbA1C) values were recorded. It was also noted if the patients sought a pre-Ramadan consultation with their healthcare professionals, visited the hospital during Ramadan, or if they had a post-Ramadan follow-up. Patients were questioned if they sought advice from their doctor or Imam, the local religious leader, if they could fast during Ramadan, and if pre-Ramadan counselling was done by their physicians. The patients were categorised into 'very high risk', 'high risk' and 'moderate risk' categories in accordance with the guidelines of International Diabetes Federation (IDF) and Diabetes and Ramadan Alliance (DAR)<sup>11</sup> (Table 1). The pre-Ramadan medication and if a change was made to the medication during Ramadan was noted. We also assessed patients' knowledge about whether checking blood sugars invalidated the fast, the level of hypoglycaemia and hyperglycaemia at which the fast had to be broken. We evaluated if the patients had any episodes of hypoglycaemia or hyperglycaemia during Ramadan. It was noted if the patients had to be hospitalised during Ramadan due to complications of fasting such as hyperglycaemia, hypoglycaemia, diabetic ketoacidosis, hyperglycaemic hyperosmolar state, dehydration and thrombosis. A note was also made about the change in physical activity, sleep, caloric and fluid intake during

Ramadan. We recorded if the patients fasted also during the year other than the month of Ramadan.

Data was analysed using SPSS 23. Continuous variables were reported as means  $\pm$  standard deviation (SD), and categorical variables as frequencies and percentages. Chi-square test was applied to find association of different categorical variables and t test was used to find association between continuous variables.  $P < 0.05$  was taken to be significant.

## Results

Of the 272 patients 176(64.7%) were females. The overall mean age was  $50.7 \pm 10.98$  years; 147(54%) were illiterate; 29(10.7%) had education of intermediate and above; monthly income was  $<Rs20,000$  for 130(47.8%);  $Rs 40-60,000$  for 105(38.6%); T2DM was predominant 269(98.9%); mean number of fasts kept were  $22 \pm 10.61$ ; and 141(51.84%) fasted for the whole month.

Of the total, 120(44.1%) individuals consulted their doctors pre-Ramadan; 42(15.4%) consulted their local imams. Out of those who reached out to their healthcare providers, counselling was received by 105(87.5%).

A history of hypoglycaemia 3 months prior to Ramadan was obtained in 34(12.5%) cases; 21(7.7%) had history of recurrent hypoglycaemia; 12(4.4%) had history of hypoglycaemic unawareness; 23(8.5%) had diabetic ketoacidosis, hyperglycaemic hyperosmolar state, or admission due to raised blood glucose; 94(34.6%) had history of sustained hyperglycaemia. One (0.36%) patient fasted during pregnancy.

In terms of categorisation, 41(15.1%) fell into the very high risk category, 109(40.1%) high risk and 122(44.9%) moderate/low risk category. The risk category had a significant negative correlation with level of education ( $p < 0.0001$ ) and income ( $p = 0.002$ ) (Table 2).

Overall, 33(12.1%) patients had a change in medication during Ramadan. Of these, 22(66.6%) patients had visited their healthcare professionals prior to Ramadan, while 11(33.3%) did it without proper medical advice. In patients visiting their healthcare professionals, a change in medication was more likely ( $p = 0.006$ ). Of the patients, 56(20.5%) were on insulin therapy, and 12(21.4%) had a change in the insulin dose; 8(66.6%) of these had visited their physicians prior to Ramadan, while 4(33.3%) changed their dose without proper medical advice ( $p = 0.106$ ).

Knowledge assessment showed 83(30.5%) patients knew that checking blood glucose during fasting does not invalidate the fast; 28(34%) of these patients had been counselled pre-Ramadan ( $p = 0.074$ ). Further, 34(12.5%)

**Table-1:** IDF-DAR categories for patients with type 2 diabetes.<sup>11</sup>

Risk category and religious opinion on fasting	Patient characteristics
<b>Category 1: Very high risk</b> listen to medical advice <b>must</b> not fast	One or more of the following 1. Severe hypoglycaemia within the 3 months prior to Ramadan 2. Unexplained DKA within the 3 months prior to Ramadan 3. Hyperosmolar hyperglycaemic coma within the 3 months prior to Ramadan 4. History of recurrent hypoglycaemia 5. History of hypoglycaemia unawareness PoorlycontrolledT1DM 6. Acute illness 7. Pregnancy in pre-existing diabetes, or gestational diabetes treated with insulin or SUs 8. Chronic dialysis or chronic kidney disease stage 4 & 5. 9. Advanced macrovascular complications 10. Old age with ill health
<b>Category 2: High risk</b> listen to medical advice <b>should</b> not fast	One or more of the following 1. Type 2 diabetes with sustained poor glycaemic control 2. Well-controlled Type 1 diabetes mellitus 3. Well-controlled Type 2 diabetes on mixed dose insulin or mixed insulin 4. Pregnant type 2 diabetes or gestational diabetes controlled by diet only or metformin 5. Chronic kidney disease stage 3 6. Stable macrovascular complications 7. Patients with comorbid conditions that present additional risk factors 8. People with diabetes performing intense physical labour 9. Treatment with drugs that may affect cognitive function
<b>Category 3: Moderate/low risk</b> listen to medical advice. Decision to use licence not to fast based on discretion of medical opinion and ability of the individual to tolerate fast	Well controlled type 2 diabetes mellitus managed with one or more of the following 1. Lifestyle therapy 2. Metformin 3. Acarbose 4. Thiazolidinediones 5. Second-generation SUs 6. Incretin-based therapy (DPP-4inhibitors or GLP-1 RAs) 7. SGLT2inhibitors 8. Basal insulin

DAR - Diabetes and Ramadan International Alliance; DKA - diabetic ketoacidosis; DPP-4 - dipeptidylpeptidase-4; GLP-1 RA - glucagon like peptide-1 receptor agonist; IDF - International Diabetes Federation; SGLT2 - sodium-glucose co-transporter-2 ; SU - sulphonylurea

patients knew the level of low blood glucose at which the fast must be broken; 25(73.5%) had been counselled prior to Ramadan (p<0.0001). Also, 31(11.4%) patients knew the level of high blood glucose at which the fast has to be broken; 23(74.2%) of them had counselling prior to Ramadan (p<0.0001). Finally, 76(27.94%) patients checked their blood glucose during Ramadan which correlated

**Table-2:** Association of the individuals' risk category with their income and level of literacy

Demographic Details	Risk Category			Chi square significance
	Very high risk	High Risk	Moderate risk	
<b>Education</b>				
Illiterate	30	69	48	p<0.0001
Primary	7	18	35	
Secondary	2	12	22	
Intermediate	0	11	18	
<b>Income</b>				
<Rs 20,000	30	45	55	p=0.002
Rs 20-40,000	8	45	52	
>Rs 40,000	1	20	16	

significantly with their knowledge of the fact that checking blood glucose did not invalidate the fast (p<0.0001).

A total of 35(9.4%) patients had hypoglycaemia during Ramadan; 13(37%) of whom had 2-3 episodes and 3(8.5%) had more than that. Hyperglycaemia >300mg/dl was observed in 42(15.4%) patients. Complications as a result of fasting led to hospitalisation in 17(6.25%) individuals; 3(17.6%) had hypoglycaemia, 2(11.8%) had hyperglycaemia, 8(44.4%) went into diabetic ketoacidosis or hyperglycaemic hyperosmolar state, and 4(23.5%) were admitted with dehydration. Out of these 17 individuals, 2(11.8%) were in the very high-risk category, and 11(65%) were in the high risk category.

In 94(34.6%) patients physical activity increased, and in 79(84%) of these it was due to the 'taraweeh' prayers; in 36(13.2%) patients it was reduced; and in 142(52.2%) it remained constant. Sleep was disturbed in 71(26.1%) patients. Caloric intake increased in 39(14.3%), reduced in 23(8.5%),

stayed more or less the same in 210(77.2%) individuals. Fluid intake increased in 105(38.6%), reduced in 33(12.1%) and remained the same in 134(49.3%) patients. Overall, 61(22.4%) individuals visited the hospital during Ramadan, while post-Ramadan follow-up was 199(73.2%). The mean pre-Ramadan weight was 72.97±10.60 and in 182(66.9%) cases it remained constant.

The mean HbA1C pre-Ramadan was 9.13±2.15 which post-Ramadan fell to 8.91±2.05 (p<0.0001).

**Discussion**

In the landmark EPIDIAR study, data was gathered from 12,243 Muslims living with diabetes across 13 countries in 2001<sup>3</sup> and it found that 37% T2DM patients were self-monitoring their glucose level during Ramadan. In the current study, this percentage was 27.94% (n=76).

Like the results of EPIDIAR, our study also revealed that in

over half of the population there was no change in physical activity, sleep, fluid or caloric intake. However, where the EPIDIAR study found that only 62% of the patients had been counselled by their physicians, our study found that out of those who had visited the hospital pre-Ramadan 87.5% (n=105) had received guidance. This is perhaps due to the growing awareness of the physiology and adjustments in lifestyle and medication that is required during this period. It is a result of the awareness produced by the EPIDIAR study about the lack of scientific evidence that exists regarding both patient practices and physician knowledge as well as evidence-based adjustments in medications that is required during Ramadan that a number of recommendations and educational programmes came up to address this issue.<sup>12-14</sup>

The CREED study was a multi-country, retrospective, observational study of the management and outcomes of patients with T2DM during Ramadan. It was conducted in 2010 across 13 countries and the patient pool was 3250. It identified intercountry differences in the guidance offered by the physicians and the differences in their ideas of risk stratification perhaps due to the dearth of a unified and accepted guidance given by an authority. This paved the way for IDF DAR recommendations of 2016.<sup>11</sup> The CREED study found that 94.2% of the patients with diabetes fasted for at least 15 days in Ramadan and 62.3% fasted every day of the month. In our study 141 (51.84%) patients fasted for the whole month. In our study 44 (16.2%) patients fasted at other times of the year as well. In the CREED study this was 29.9% while different proportions were reported from different countries, ranging from 8% in India to 46% in Malaysia.<sup>14</sup>

Sleep patterns are often altered during Ramadan. The impact of Ramadan on sleep includes decreased total sleep time, delayed sleep, decreased sleep period time, decreased rapid eye movement (REM) sleep duration, decreased proportion of REM sleep, and increased proportion of non-REM sleep.<sup>15</sup> Sleep deprivation itself is associated with decreased glucose tolerance. Correlation between sleep quality and duration with insulin resistance (IR) and glycaemic control is of current medical interest.<sup>16</sup> In our study, 71 (26.1%) subjects had disturbed sleep during Ramadan. During Ramadan there are also changes in the circadian rhythm of cortisol and compared with non-Ramadan period the morning levels of cortisol are lower and evening levels are higher.<sup>17</sup> This may account for the lethargy felt by the fasting Muslims during fasting.

In healthy individuals during fasting as glucose levels fall, insulin secretion is suppressed. Simultaneously glucagon and catecholamine secretions are increased, stimulating glycogenolysis and gluconeogenesis, both of which

increase the glucose levels.<sup>18</sup> Liver glycogen can produce glucose for the brain and peripheral tissues for up to twelve hours. When liver glycogen is depleted, fatty acids can be oxidised to produce ketones which can be used as a substitute fuel for the peripheral tissues, while glucose is preserved for the brain and erythrocytes.<sup>12</sup> During Ramadan each fasting period is often longer than 12 hours so that each fast is considered a period of intermittent glycogen depletion and repletion. Most individuals are in a state of ketogenesis by late afternoon. In individuals with diabetes, glucose homeostasis is disturbed both due to the pathophysiology as well as the medications used to treat the condition. When fasting, additionally there is increased IR, insulin deficiency and augmented ketogenesis. As a consequence, risks facing these individuals are heightened, which includes hyperglycaemia, hypoglycaemia, diabetic ketoacidosis (DKA), hyperglycaemic hyperosmolar state (HHS), dehydration and thrombosis.<sup>12</sup>

The current study found that 8 (2.9%) patients were admitted with DKA or HHS. A multi-country observational study found that the admissions for DKA were higher in Ramadan and Shawal compared to other months.<sup>19</sup> Fluctuations in glucose levels have been associated with oxidative stress, platelet activation and a rise in cardiovascular diseases in individuals with diabetes.<sup>20</sup> In our study, no patient was admitted with thrombosis.

Individuals who are on insulin therapy can fast safely if the therapy is modified and the blood glucose is monitored stringently.<sup>21,22</sup> In our research the three individuals who had type 1 diabetes fasted safely during Ramadan. In a study involving 33 adolescent children who fasted during Ramadan, 60.6% completed their fasts without any serious problems.<sup>23</sup> Another study involving 21 adolescents also found that 76% fasted for at least 25 days without any serious issues.<sup>24</sup>

The current study found that a high proportion of patients who fasted were in the very high risk 41 (15.1%) and high risk categories 109 (40.1%). Many of these individuals chose to fast even against medical advice and in such circumstances such patients must be given adequate education and medication adjustment so that fasting can be made as safe as possible.<sup>12</sup>

There is a misconception by some Muslims that pricking for the purpose of checking blood glucose invalidates the fast.<sup>25</sup> In our study 189 (69.4%) patients also held this belief, demonstrating poor patient knowledge which could also be due to poor recommendations on the part of the healthcare providers. A study across Pakistan demonstrated poor knowledge in at least one-third of the physicians encompassing the basic principals in the management of

diabetes during Ramadan.<sup>26</sup> In the current study, 12.5% of the patients who had visited their healthcare providers prior to Ramadan did not receive any counselling for fasting. Only 30(25%) of those who visited the doctors had a change in medication or insulin. A study conducted in Karachi reported that 70% of the patients were monitoring blood glucose during Ramadan, and incidence of hypoglycaemia was low at 3.1%.<sup>27</sup> Proper pre-Ramadan counselling, education, medication adjustment and monitoring blood glucose can enable individuals to fast safely during Ramadan. This was also demonstrated by the Ramadan Diabetes Prospective Study carried out in Pakistan.<sup>28</sup>

In the current study, there was a significant decline in HbA1C level. In a study carried out in Lahore the mean glucose also declined during Ramadan fasting.<sup>29</sup> Another research conducted in Karachi also found an improvement in fasting glucose, lipid profile, and blood pressure control during fasting.<sup>30</sup>

It is expected that the pitfalls identified would pave the way for larger studies addressing patient behaviour and physician knowledge and practices so that comprehensive local guidelines for fasting during Ramadan can be formulated for diabetics

## Conclusion

Suboptimal practices were found in diabetic patients who fasted along with a lack of basic knowledge encompassing the principals of fasting. Physician practices also needed optimisation.

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