## **ORIGINAL ARTICLE**

# A Snapshot of Risk Stratification of Diabetic Patients Fasting during the Month of Ramadan

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#### **ABSTRACT**

**Objectives:** To get a clinical snapshot of the diabetic patients who planned to fast during the month of Ramadan and to determine the ability of the RRR application to effectively risk-stratify patients.

Study Design: Observational study.

**Place and Duration of Study:** Department of Diabetes & Endocrinology, Armed Forces Hospital Al-Hada, Taif, Kingdom of Saudi Arabia from 1<sup>st</sup> April 2018 to 31<sup>st</sup> May 2018.

**Methodology:** Ninety six patients over 15 years of age with diabetes mellitus were risk stratified using standardized risk criteria were enrolled. Detailed analysis of the information was performed to paint a clinical landscape of the patients who intended to fast

Results: Seventy four percent of the patients were type 2 diabetics, 11% GDM, 31% were between 60-70 years and 17% had diabetes for more than 20 years. 17% of participants had serious complications during the last three months before Ramadan including hypoglycemia, Diabetic Ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS). 59% had chronic diabetic complications. 28% of patients were on both insulin and oral hypoglycemic agents (OHA) together and 16% on high risk medications. 25% of patients had an HbA1C of more than 10%. Pertaining to the previous Ramadan experience 19% disclosed having serious complications in the past. 6% were categorized as low risk individuals, 76% as moderate, 6% high and 12% as very high risk.

**Conclusions:** Astonishingly all the patients advised to refrain from fasting insisted on fasting. Considering the latest IDF numbers the above calculated percentages would translate into very huge numbers who are in serious jeopardy. In order to prevent serious consequences it is highly recommends that evidence based and validated risk stratification strategies are implemented in routine clinical practices.

Keywords: Diabetes mellitus, Fast, Hypoglycemia, High risk patients

#### INTRODUCTION

Out of a 193 countries on the United Nations list, 57 are predominantly Muslim, a population of approximately 2.08 billion about 25 % of global population. About 8.3% of adult pervasiveness of diabetes universally exists accounting for 382 million individuals<sup>2,3</sup> together with the outcomes of the populationcentered Epidemiology of Diabetes and Ramadan (EPIDIAR) study, which disclosed that 43% of patients with type 1 diabetes and 79% with type 2 diabetes fast during Ramadan. 4 About 40-50 million individuals with diabetes globally fast during Ramadan. Merging EPIDIAR statistics with the latest approximations for the worldwide Muslim population and overall diabetes prevalence it proposes that there are 148 million Muslims with diabetes across the world, and 116 millions of them may fast during Ramadan. The CREED study data has disclosed that 94.2% of Muslims with type 2 diabetes who are fasting during Ramadan fast for at least fifteen days and several of them fast daily.5

The EPIDIAR study<sup>4</sup> established that the alteration in eating habits during Ramadan is related to 4.7-times augmented hazard of serious hypoglycemia among type 1 diabetes and 7.5-fold in type 2 diabetes. 4,5 Outcomes of EPIDIAR study also displayed a fivefold upturn in the frequency of severe hyperglycemia during Ramadan in patients with type 2 diabetes, and around threefold increase in the incidence of severe hyperglycemia with or without ketoacidosis in patients with type 1 diabetes.4 Individuals with diabetes, particularly type 1 diabetes, are at a higher threat for occurrence of diabetic ketoacidosis, mostly if they were unacceptably hyperglycemic pre Ramadan.<sup>5</sup> Furthermore, hyperglycemia can cause osmotic diuresis and enhance volume reduction. Shrinkage of the intravascular volume may also contribute to hypercoagulability in patients with diabetes who already have high levels of clotting factors, diminished endogenous anticoagulants and compromised fibrinolyis.<sup>6</sup> Increased blood thickness secondary to dehydration may also boost the risk of clotting, stroke and retinal vein obstruction.7

Professional view endorses that if a patient intends to fast, the initial action is to perform a risk staging. Thus patients are grouped into low, moderate, high, and very high risk.<sup>8</sup> Based on

the current International Diabetes Federation guidelines<sup>9</sup> a free smart phone risk stratification and management application has been designed and launched for both iOS and android devices.<sup>10</sup> The application contains a built-in artificial intelligence calculation logic based on evidence-based anthropometric, clinical and biochemical risk criteria.

## **METHODOLOGY**

This observational study was conducted in the Endocrinology and Diabetes Clinic at Armed forces hospital Al-Hada, Taif, Saudi Arabia. This is the main regional tertiary care center for armed forces personnel and their families. Patients were recruited during the period from April 2018 to May 2018 which was one month prior to Ramadan fasting. A written informed consent and Institutional Review Board approval was obtained. Hundred Saudi individuals with a primary diagnosis of type 1, type 2, gestational diabetes mellitus, and age of more than 15 years who wished to fast during the month of Ramadan, had a valid hospital file and were from Taif Makkah region were included in the study. Non-diabetics, paediatric age group, clinically unstable inpatients, mentally subnormal and unsteady patients, were excluded from the study. Moreover, patients who did not have a valid file and living outside Taif Makkah region were also excluded as it was not possible to investigate them for follow up.

Initially, patients were assigned a serial number and given a questionnaire detailing their personal data, including their name, phone number and medical ID. Relevant medical history comprising of; age, gender, profession, type and duration of diabetes was also documented. Presence of acute complications including diabetic ketoacidosis, hypoglycemia and hyperglycemic hyperosmolar syndrome in the last three months was confirmed. Chronic diabetic complications i.e., ischemic heart disease, peripheral vascular disease, diabetic neuropathy, chronic kidney disease, end stage renal disease (ESRD) were confirmed. A detailed medication history was taken and all the anti-diabetic medications recorded.

Patients were examined and anthropometric data consisting of height, weight and BMI were calculated. Blood pressure was

measured in the sitting position as standard recommendations. Blood samples were taken for HbA1C (glycosylated haemoglobin), total cholesterol, LDL cholesterol, triglycerides, HDL cholesterol, urea and creatinine. The above risk criteria were entered into the Ramadan Risk Rate Calculator. <sup>10</sup> (Fig 1) to assess the risk category of the individual patient so that appropriate advice could be given to the patient. Data analysis was performed using SPSS-20

## **RESULTS**

The study enrolled approximately 100 patients with the baseline characteristics as shown in Tables 1-2. Age distribution 15-70 years (Fig. 2) with 31% males and 69% females were noted. About 74% had a history of type 2 DM, 9% type 1 DM and 11% GDM (Fig. 3). As far as HBA1C was concerned 37% had <7, 23% had 7.1-8, 13 % had 8.1-10, 17% had 10.1-12 and 7% >12 (Fig 4). About 36% of patients were diabetics for less than 5 years, 13% for 5-10 years, 29% for 10-20 years and 17% for more than 20 years (Fig 5). A total of 76% had no acute complications in the last 3 months before Ramadan, 14% had experienced hypoglycemia, 2 % had DKA (Diabetic Ketoacidosis) and only 1% had history of HHS (hyperosmolar hyperglycemic state). 59% of patients had various chronic complications of diabetes mellitus, and 41% had none. As far as the treatment was concerned, 10% were on diet alone, 22% on low risk medications, 18% on multiple OHA, 28% on insulin and OHA both and 16% were on high risk medications. Concerning the previous Ramadan experience, 18% of patients reported no previous experience, 57% did not have any complications previously and 19% were admitted having serious complications in the past. Relevant parameters were plugged into the Ramadan Risk Rate calculator and individual patient was risk stratified. According to the RRR calculator 6% were categorized as low risk individuals, 76% as moderate, 6% high and 12% as very high risk.

## **DISCUSSION**

There is irrefutable evidence that diabetes during Ramadan is both quantitatively and qualitatively a significant problem with serious consequences. Converting latest International Diabetes Federation (IDF) data into latest demographics of diabetes in the Muslim population reveal that out of a total of 148 million diabetics amongst Muslims some 116 million individuals fast during Ramadan.<sup>5</sup> This results in some very serious consequences including severe hypoglycemia, DKA, HHS, thrombosis and retinal vein obstruction.<sup>4,6,7</sup>

This is for the first time that a root cause analysis has been attempted to find the actual source of these complications. This study clearly revealed that 18% of the patients were categorized as high or very high risk patients. About 17% of participants had serious acute complications i.e. DKA, dangerously low hypoglycemia and HHS within 3 months before Ramadan fasting. About 59% had chronic diabetic complications and some of them had very serious problems including ESRD and were on dialysis. As far as treatment was concerned 28% of individuals



Fig. 1: Ramadan Risk Rate Calculator

Table 1: Demographic data

Parameter

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Gender		
Male	33	31.0
Female	63	69.0
Age (years)		
15-20	3	3.1
21-30	5	5.2
31-40	15	15.6
41-50	13	13.5
51-60	30	31.3
61-70	30	31.3
Daily activities		
Sedentary	26	27.1
Mild	41	42.7
Moderate	29	30.2
Severe	-	-
Type of diabetes		
Type 1	10	10.4
Type 2	75	78.1
GDM	11	11.5
Duration of diabetes (years)		
<5	36	36.0
5-10	14	13.0
10.1-20	29	29.0
>20	17	17.0
HbA1c		
<7	36	37.5
7-8	23	23.98
8.1-10	13	13.54
10-1-12	17	17.7
>12	7	7.3

Table 2: Descriptive statistics of the patients

Parameter	Mean±SD
Weight (kg)	80.43±14.63
Height (cm)	158.53±9.67
BMI (kg/m <sup>2</sup> )	33.85±4.72
Sys BP (mmHg)	125.93±17.9
Dia BP (mmHg)	74.41±11.63
HbA1c (%)	8.2±10.12
LDL (mmol/L)	2.78±1.31
HDL (mmol/L)	1.11±0.68
Cholesterol (mmol/L)	4.74±1.92
TG (mmol/L)	1.62±0.77
Urea (mmol/L)	5.564±2.35
Creatinine (mmol/L)	83.65±21.57

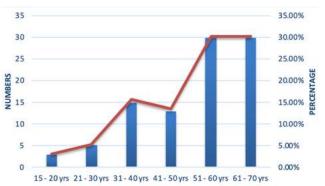


Fig. 2: Age distribution

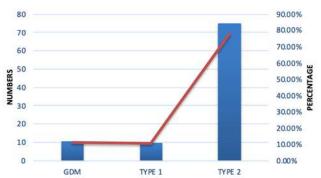


Fig. 3: Type of diabetes mellitus

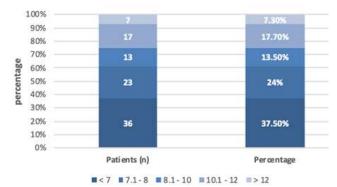


Fig. 4: HbAlc

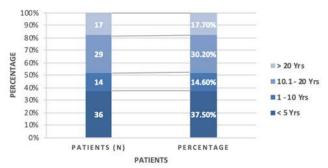


Fig. 5: Duration of diabetes mellitus

were on both insulin and OHA together and 16% were on high risk medications, the lot of patients had uncontrolled diabetes and 25% of patients had HbA1C of >10%. According to the latest IDF, DAR guidelines recommendations these patients should not be allowed to fast. Astonishingly all of these patients were at high or very high risk and advised to refrain from fasting, but they insisted on fasting against medical advice. If these high risk feature percentages are converted into absolute numbers they would translate into some huge figures. It seems that roughly 21 million patients with diabetes who are high to very high risk may be fasting against medical advice. Evidently there are five big areas which are contributing to this enormous volume of high risk patients. Apparently, a staggering 32 million diabetics who fast are on both insulin and oral hypoglycemic agents with 18 million on high risk medications, approximately 29 million patients undertake fasting with their HbA1C above 10 percent, there are about 19 million individuals who had serious acute complications within last three months before fasting and a lot of individuals have chronic diabetic complications including some 10 million with chronic renal disease, End Stage Renal Disease and patients on dialysis. If serious mortality and morbidity amongst diabetic patients during Ramadan has to be prevented then these are some of the areas which need to be addressed very vigilantly.

It is worth mentioning that these numbers should be taken very cautiously and may be an overestimation of the reality. This was a single centered study from a tertiary care hospital and patients coming to a specialized endocrine clinic have more complications and may cause the miscalculations. Having said that it should not be forgotten that according to IDF report 80% of diabetics are coming from nations with middle and low income populations and these countries are facing a firestorm of ill health and they have very little resources to protect their populations. It may not be surprising that these numbers may be a close reflection of the actual reality.

It has been emphasized that if a patient has consented to fast the first thing that needs to be done is risk stratification followed with Ramadan focused education. This may be available to patients in affluent nations but is non-existent in third world countries which are facing an epidemic of diabetes. In a big observational study, patients who fasted and did not attend any organized educational session had a four times escalation in hypoglycemia episodes, however those who joined an educational program focusing on Ramadan had a substantial reduction in hypoglycemicepisodes. This could be one of the reasons of high rate of complications in diabetic patients who fast during the month of Ramadan.

#### CONCLUSION

This present study has uncovered some very astonishing and appalling statistics which need to be further substantiated with more robust multi-centered and multinational studies. However, the role of risk stratification and Ramadan education cannot be over emphasized and should be implemented in current practice urgently. To reach out the patients in the community effectively and directly the role of the smart phone applications will be very vital. It cannot be emphasized enough that close proximity of science and religion hand in hand in managing diabetes during Ramadan would go a long way in saving hundreds of lives and may change the mindset and attitudes of the Muslim population.

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