

Type 1 diabetes and fasting during Ramzan

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ABSTRACT

Fasting is one of the five pillars of Islam, and consequently, even the Muslims with diabetes prefer to fast during Ramadan, irrespective of the healthcare implications. However, this fast can be very difficult to manage in patients of Type 1 diabetes (T1DM), who are on insulin therapy. Risks of diabetic ketoacidosis, severe hypoglycaemia, hyperglycemia, dehydration and thrombotic episodes are increased. Lack of proper pre-fast assessment, management and diabetes education have been stumbling blocks in facilitating Ramadan fasting in type 1 diabetes patients. Recent developments like the use of insulin pumps and analogs and recognition of the importance of structured diabetes education and assessment to select the patients best suited for the rigors of fasting, have wrought a sea change in the usually negative approach of doctors towards Ramadan fasting in patients with T1DM. Sophisticated therapeutic options like smart insulins, can provide safer and more convenient options for management of Type 1 diabetes during Ramadan, a few years down the line. More studies are also needed to explore other options like GLP-1 agonists, alpha glycosides inhibitors and DDP-4 agonists, as adjuncts to insulin therapy.

Key words: Children and adolescents, insulin pumps, ketoacidosis, smart insulins, type 1 diabetes (T1DM)

INTRODUCTION

Ramzan, the 9th month of the Islamic calendar, is synonymous worldwide, as the month of fasting. During this month, a majority of the more than 1 billion Muslims worldwide observe an absolute fast from dawn to dusk without intake of any food or drink. People whose health can be negatively impacted by fasting are exempt from it, but many people still insist on fasting, because the Ramzan fast is one of the five pillars of Islam. Data from the epidemiology of diabetes and Ramadan (EPIDIAR)^[1] study, which was conducted across 13 countries in 2004 and included 12,243 participants, who fasted during the month of Ramzan, indicated that 42.8% of patients with type 1 diabetes reported fasting at least 15 days during Ramzan. The Ramzan fast typically consists of a fasting

period which can extend upto 12 h in summer and 8-9 h in winter. Once the fast is broken, it is followed by a heavy evening meal Iftar and a lighter meal Saher, before sunrise, interspersed with snacks. The meals are also traditionally rich in fats and carbohydrates. The International Consensus Meeting^[2] held in Morocco in 1995 defined suitable criteria for fasting and exempted people with type 1 diabetes from fasting. However, a sense of appreciation of their religious responsibilities and a desire to fast along with other adherents of the faith has ensured that a large majority of Muslims with type 1 diabetes mellitus (T1DM) continue to fast during Ramzan.

ALTERED PATHOPHYSIOLOGY DURING FASTING

While fasting, circulating glucose levels decrease, leading to decreased secretion of insulin and increase in levels of counter regulatory hormones and increasing glycogenolysis and gluconeogenesis. Further prolonged fasting leads to adipose tissue breakdown and ketogenesis. Normally, the body has enough glycogen stores to support fasting for upto 10-12 h, before gluconeogenesis and ketogenesis become predominant. In patients with T1DM, these mechanisms become modified by various factors like

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hypoglycemia unawareness and autonomic neuropathy leading to lack of epinephrine rise during episodes of hypoglycemia and failure of glucagon secretion to increase, during hypoglycemia. Excessive decrease of insulin dose during fasting can precipitate hyperglycemia and diabetic ketoacidosis (DKA) due to excessive glycogen breakdown and increased gluconeogenesis and ketogenesis. Other studies have demonstrated a rise in high-density lipoprotein (HDL) levels and a fall in triglycerides during fasting, while blood pressure remained unchanged.^[3]

Complications of fasting

Fasting during Ramzan is fraught with multiple medical problems for patients with T1DM. The risks of fasting include hypoglycemia, hyperglycemia, DKA, and dehydration.^[4]

Hyperglycemia

Hyperglycemia is one of the most common problems observed during this month. A fear of hypoglycemia on part of both the doctors and the patients, coupled with carbohydrate and calorie rich meals, associated with an abrupt change in meal times and use of insulin contributes to this hyperglycemia. Water is also prescribed during the fast throughout this month. While fasting, eating and drinking are exclusively at night. Further, the management of children with diabetes who choose to fast during Ramzan, also poses a challenge, as the majority of guidelines and data on safety and metabolic impact of fasting are based on practice and studies on adult population. The EPIDIAR study^[1] reported a fivefold increase in the incidence of severe hyperglycemia (requiring hospitalization) and an approximate threefold increase in the incidence of severe hyperglycemia with or without ketoacidosis in patients with type 1 diabetes. However, there is no information linking yearly episodes of a month longfast and diabetes-related complications.

Diabetic ketoacidosis

Patients with type 1 diabetes, who fast during Ramzan are at a greater risk for developing diabetic ketoacidosis. This is plausible in the setting of pre-fast poor control and compliance, carbohydrate rich meals, the tendency to reduce insulin doses for fear of hypoglycemia, and in the setting of infection. However, data which supports the increased incidence of DKA during the Ramzan fasting is scarce. In fact, studies by Kadiki *et al.*,^[5] Abusrewil *et al.*,^[6] and Rafik^[7] have reported rates of incidence of DKA during Ramzan fasting, which are similar to the general population incidence rates. However, given the increased risk factors for DKA during fasting and the high morbidity and mortality associated with DKA, appropriate education about recognizing DKA and vigilance for its symptoms, must be strictly enforced during Ramzan fasting.

Dehydration

Multiple factors are responsible for dehydration during fasting, including a restriction on fluid intake while fasting, osmotic diuresis due to hyperglycemia, fasting during summer, and increased physical activity and associated sweating. Dehydration, especially when severe, can manifest as postural dizziness; orthostatic hypotension leading to falls and fractures, especially in the older people; and the most dreaded complication of thrombosis. Dehydration precipitates a hypercoagulable state due to contraction of intravascular volume and increase in the viscosity of blood. Diabetes itself is a prothrombotic state due to decreased fibrinolysis and endogenous anticoagulants and the rise in a few clotting factors. This thrombotic state can manifest as a cerebrovascular accident, myocardial infarction, or even as retinal vein occlusion.

Hypoglycemia

Fasting can precipitate hypoglycemia due to a reduction in oral intake. The impact of fasting during Ramzan on incidence of hypoglycemia and mortality is not well known. The EPIDIAR study^[1] found that the change in eating patterns during Ramzan increased the risk of severe hypoglycaemia 4.7-fold (from 3 to 14 events per 100 people per month) in type 1 diabetes. Further, severe hypoglycemia was probably under reported in this study, because only episodes requiring hospitalization were considered. Another study by Loke *et al.*,^[8] found that relative risk (RR) of hypoglycemia of 1.60 during Ramzan fasting compared with a nonfasting period of equivalent length. Good metabolic control (HbA1c < 8%) and old age (> 60 years) increased RR more than twice, while taking breakfast prior to fasting reduces RR to less than half. These RR are lower than what have been reported by EPIDIAR.^[1] Hypoglycemia is of special concern in children and adolescents due to its neurocognitive impact. Some of the factors which can influence the severity of hypoglycemia while fasting are: The age of patient with T1DM, duration of diabetes, prior glycemic control, level of diabetes education, and the type of insulin being used. In a study by Kadiri *et al.*,^[9] when lispro was compared with regular insulin in T1DM patients on a Ramzan fast incidence of hypoglycemia (15 episodes for lispro vs 31 for regular insulin), frequency of hypoglycemia (0.7 ± 0.19 episodes for lispro vs 2.26 ± 0.36 episodes/patient/30 days for regular insulin), and nocturnal hypoglycemia (five episodes for lispro vs 27 for regular insulin) were lower with lispro; while compliance with recommended time of insulin injection was better, thus underlining the advantages of rapid acting analogs over regular insulin in fasting patients with T1DM.

Data about impact of Ramzan fasting on chronic complications of diabetes is very sparse.

PRE-RAMZAN MEDICAL ASSESSMENT

Patients with T1DM who plan to fast during Ramzan should undergo a medical assessment 2-3 months prior to fasting. This assessment should include evaluation of HbA1C, lipids, blood glucose values, and other parameters [Table 1]. Patients should also be apprised of the risks of fasting, as also the exemptions granted to patients who are not suited to fasting [Table 2]. Necessary changes in diet and exercise regimen should also be initiated at this point of time.^[10]

STRUCTURED DIABETES EDUCATION

A structured Ramzan-focused diabetes education program, is perhaps the single most important intervention for a successful Ramzan fast in diabetic patients. Unfortunately such programs are hampered by lack of awareness among patients, healthcare providers, and religious leaders. Hence, to be successful, such programs should involve an awareness campaign about fasting in patients with diabetes focusing on the mosques and community centers. Healthcare professionals should also be made aware of the recent guidelines on this subject and requisite training imparted, to deliver necessary healthcare. Religious leaders should also be involved in these campaigns.

Components of this program include:

1. Importance of self-monitoring of blood glucose (SMBG);
2. Appropriate meal choices;
3. Recognition of DKA, hyperglycemia, and hypoglycemia;
4. Avoiding excessive physical activity and dehydration promoting behavior; and
5. Cessation of fasting whenever required.

This education should be imparted in the vernacular, either singly or as group discussions at mosques, community, or healthcare centers or as brief lectures over mass media or social networks. The benefits of a well-delivered diabetes education program can extend well beyond the period of fast and can lead to a positive impact on glycemic control of patients with T1DM. In an observational study by Bravis *et al.*,^[11] patients who fasted during Ramzan without the benefit of a structured educational program suffered a 400% rise in hypoglycemic events, whereas those who attended an education program showed a significant decline in hypoglycemic events.

MANAGEMENT

[Also refer to Figure 1]

Diet

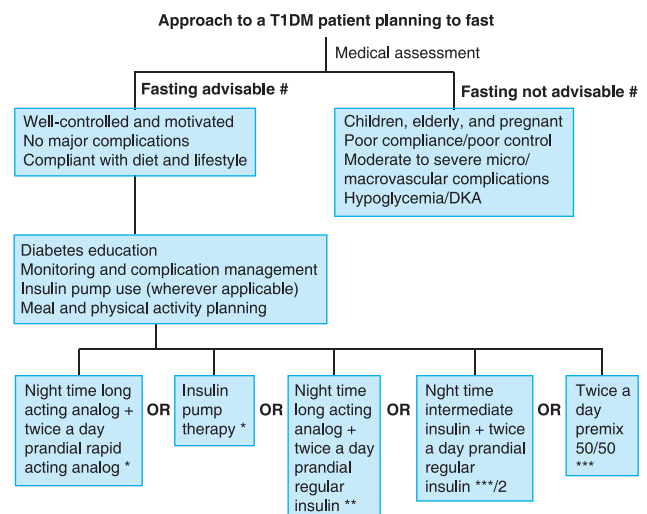
Diet should be similar to the diet being taken prior to Ramzan. Simple carbohydrate and fats should be curtailed. Rather than taking a large quantity of food in the evening meal, the evening meal can be broken down

Table 1: Prior screening for fasting (2-3 months prior to Ramzan)

Diet and lifestyle history
Diabetes education status and awareness of complications of diabetes
History of medication, diet, and medication compliance
Blood pressure record
Body mass index (BMI)
HbA1C
Fasting, pre-lunch and pre-dinner sugar chart
Fasting lipid profile
Liver and renal function tests
Evaluation for retinopathy and nephropathy (if type 1 diabetes mellitus (T1DM) duration > 3 years)
Evaluation for macrovascular complications (if T1DM duration > 3 years)

Table 2: Type 1 diabetes mellitus (T1DM) patients for whom fasting is not advisable

Children < 8 years of age
Pregnant women with T1DM
HbA1c > 10%
Poor compliance with diet and insulin
Diabetic nephropathy and severe retinopathy
Vascular disease, uncontrolled hypertension, or urolithiasis
At least 1 episode of diabetic ketoacidosis or severe hyperglycemia requiring hospitalization in the past 2 months
Four episodes of minor hypoglycemia or 2 episodes of major hypoglycemia in the past 2 months
Elderly patients with T1DM



*Tier 1, **tier 2, ***tier 2/1/2 intermediate tier, ****tier 3, #refer to text for details.
T1DM = Type 1 diabetes mellitus, DKA = diabetic ketoacidosis

Figure 1: Approach to a type 1 diabetes patient planning to fast

into a medium-sized lower calorie meal followed by a snack. Liberal intake of fluids during the night should be encouraged. The evening meal should have more simple carbohydrates to ensure normalization of blood glucose levels, while the predawn meal should comprise more of complex carbohydrates and foods like maize which release calories slowly throughout the day. The predawn meal should also be taken as close to sunrise, as is feasible.

Exercise

While some physical activity during the day is encouraged, it should not be overdone, especially in the late afternoon, as it can precipitate hypoglycemia and also lead to dehydration. Physical activity during the prayers should also be factored into the quantum of total daily exercise.

Insulin regimens

Several insulin regimens have been proposed by various studies and guidelines. When prescribing a regimen, a balance should be sought between safety, efficacy, cost of therapy, and patient acceptability. Individualization of regimens based on the pre-Ramzan glycemic record would be helpful. Some of the regimens which can be used are mentioned in Table 3^[12] and a few caveats regarding insulin therapy in Table 4.^[13]

Insulin pumps

The increasing availability and rising affordability of insulin pumps have provided a new option for managing T1DM during Ramzan. While studies about pump therapy are limited, a few studies have been published in the past 2-3 years, all of which have endorsed the efficacy and safety of insulin pumps during Ramzan. A pump is very useful in balancing the risk of hypoglycemia while fasting and the hyperglycemia which can set in after the heavy evening meal, by timely adjustments of basal and prandial insulin delivery through pump. In a study by AlBaker *et al.*,^[14] T1DM patients on insulin pump, when compared to patients on multiple daily insulin injections (MDII) or premix insulin, were able to complete their fasting with minimal episodes of mild hypoglycemia (two episodes per

patient), no episodes of hypoglycemia requiring assistance, and no emergency room (ER) visits. They also had better biochemical profiles than patients on premix insulin and profiles comparable to patients on MDII. In another study by Khalil *et al.*,^[15] patients on pump had no change in basal insulin requirements from the prefasting period, had very few episodes of minor hypoglycemia which were easily managed by titration of doses and no episodes of major hypoglycemia, thus underlining the advantages of pump therapy. However, to use a pump during Ramzan, the patient needs to be educated about the pump, motivated to monitor blood glucose frequently, and should also be able to afford pump therapy. If these limitations are overcome, insulin pump seems to provide the best possible solution for control of sugars during Ramzan fasting with minimal complications.

FUTURE PERSPECTIVES

Smart insulins

These comprise a new type of insulin delivery system, based on nanotechnology. These glucose-responsive controlled insulin delivery systems are based on the agglomerated vesicle technology (AVT), which is a chemically cross-linked agglomerate of liposomes loaded with insulin.^[16] The break-up of these chemical cross links can be initiated by high blood glucose levels, thus releasing insulin from the agglomerate and restoration of blood glucose to normal levels. The quantity of insulin released is proportional to the blood glucose level and thus, the hypoglycemia generally associated with insulin use can be avoided. Initially, a lectin, concanavalin-A was used as a cross-linker,^[16] but due to its toxicity and inflammatory effects was discarded and boronic acids are now being explored. In addition, to being nontoxic and noninflammatory, more so when conjugated with lipid poly ethylene glycol (PEG), boronic acids^[17] have also been found to have a basal untriggered release of insulin, a property not found with concanavalin-A. This helps to avoid a build-up of cross-linked insulin in the body and also ensures a basal insulin release. These insulins are at least a decade away

Table 3: Insulin regimens

Basal bolus Analog*	Basal-bolus Conventional***/2	Twice daily regimen***	LA analog + regular insulin**	Insulin pump*
Single dose of long-acting analog in late evening with 2 doses of prandial short acting analog Correcting doses of short acting analog as required, based on SMBG	Single dose of NPH in late evening with 2 doses of prandial regular insulin	To use morning dose of premix/split mix regimen before evening meal and use only short acting insulin at 0.1-0.2 u/kg before predawn meal	Single dose of long-acting analog in late evening with 2 doses of prandial regular insulin. Useful when early morning hypoglycemia is to be avoided and affordability precludes short-acting analog	Reduce basal infusion rate and increase bolus dose prior to evening and morning meals

*Tier 1 -most preferred, **tier 2 - less preferred, ***/2tierintermediate-lesspreferred - cost-cutting measure, ****tier 3 - least preferred, SMBG: Self-monitoring of blood glucose, NPH: Neutral protamine Hagedorn

Table 4: Caveats regarding insulin therapy and SMBG during Ramzan fast^[20]

Basal insulin should be reduced by upto 20% of predose
 If using premix, 50/50 can be used instead of 30/70 to avoid postprandial hyperglycemia
 As a starting point, transfer morning premeal dose to evening and take half of pre-dinner dose before the dawn meal. Titrate according to SMBG
 Adjust insulin doses every 3 days or more frequently, if required
 Insulin therapy should be supported by frequent SMBG
 Blood glucose levels should be monitored 30 min before and 2 h after evening meal, 2 h after predawn meal, at midday, and whenever symptoms suggestive of hypoglycemia or hyperglycemia occur
 End fast if blood glucose < 60mg/dl or > 300 mg/dl
 Avoid fasting on sick days
 Use of carbohydrate counting and correction doses of short acting insulin as required

SMBG: Self-monitoring of blood glucose

from commercial development, but have the potential to be useful for treatment while fasting during Ramzan and avoid hypoglycemia.

DI PEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS AND ALPHA-GLUCOSIDASE INHIBITORS (AGIS)

Postprandial hyperglycemia, especially after the evening meal is one of the major concerns of the Ramzan fast. This can be countered by increasing the insulin dose, but sometimes, postprandial hypoglycemia can be precipitated, especially in T1DM patients with autonomic neuropathy or nephropathy. Recently a few studies have explored DPP4 inhibitors in T1DM. In a study by Hari Kumar *et al.*,^[18] T1DM patients who used insulin and sitagliptin had lower insulin requirements, lower body mass indices (BMIs) and HbA1C and a nonsignificant decrease in the incidence of hypoglycemia when compared to users of insulin alone. Another study by Ellis *et al.*,^[19] showed improved measures of glycemic control, including mean blood glucose and time in euglycemic range when sitagliptin was used along with insulin. Another study by Sharifi *et al.*,^[20] demonstrated lower HbA1C, fasting and postprandial glycemic values along with reductions in total cholesterol and triglycerides, when acarbose was used along with insulin. While none of these studies were conducted during Ramzan fasting, these studies do seem to suggest DPP4 inhibitors and AGIs as viable add-ons to insulin therapy in T1DM patients on a Ramzan fast.

COMPARISON OF THE VARIOUS INSULIN REGIMENS

Because a majority of studies on diabetes management during Ramadan have been performed in children, there is very little evidence to suggest the superiority of one

regimen over the other. Most of the studies dealing with Ramadan fasting have included very few subjects and have faced logistic issues due to quite a few subjects breaking the fast because of hypoglycemia. Taking into account the little evidence at our disposal, some of the factors that can aid in selecting an appropriate regimen are age, risk of hypoglycemia, technological familiarity, and affordability.^[21] Among the rapid acting insulins, in comparison to recombinant insulins, analogs have actually proven to cause less hypoglycemia due to their shorter duration of action. They also do not need to be taken half an hour before the meal, which confers a major advantage, especially in a setting where a child who has fasted all day long, would force to wait for half an hour after Iftar before having a meal, if on recombinant insulin.

In a study by Khairallah *et al.*,^[22] the use of insulin glargine along with rapid acting analogs caused a 28% reduction in the dose of insulin, with no worsening of glycemic control and without major hypoglycemia or DKA requiring hospitalization. In another study by Mucha *et al.*,^[23] two doses of rapid acting analog were used before dusk meal (Iftar) and dawn meal (Suhur) along with glargine at bedtime. There was no increase in hypoglycemia over the 1-day study period. However, this study could not be translated into clinical practice on account of its short duration. Another study by Al Nakhi *et al.*,^[24] reported similar findings with a combination of twice a day rapid analog and bedtime intermediate insulin. The best results however, have been reported in studies, which have utilized insulin pumps. But the high cost of therapy precludes the routine use of pumps in therapy. Taking all the reports in conjunction, the best options have been indicated in Table 3. Almost all studies have been consistent in advising a reduction in insulin dose of around 30% as compared to pre-Ramadan regimen, with greater reduction being advised prior to the dawn meal (Suhur).

In conclusion, maintaining optimum glycemic control during Ramzan fast for people with T1DM involves complex insulin regimens and frequent blood glucose monitoring geared towards ensuring that a balance between hypoglycemia and hyperglycemia and diabetic ketoacidosis is maintained. Lack of endogenous insulin secretion and the mandatory use of insulin ensure that the treatment paradigms are more complex than in people with T2DM. But a successful fast is possible, provided good pre-Ramzan glycemic control is initiated, appropriate education and preparation for the fasting period is imparted and coordination is maintained between the healthcare provider and the patient. Appropriate selection of patients for the fast is also mandatory.

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