



Enhancing Fasting Safety in Ramadan for Adults and Adolescents with Type 1 Diabetes Mellitus through Optimal Diabetes Care

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Abstract:

Background: Despite guidelines advising against fasting for individuals with type 1 diabetes during Ramadan, many choose to fast, posing risks of hypoglycemia, hyperglycemia, and diabetic ketoacidosis.

Aim: This study aimed to assess the effects of optimal care, including Ramadan-focused education, flash glucose monitoring, dietary advice, and treatment adjustment, on the safety of Ramadan fasting in individuals with type 1 diabetes.

Methods: Thirty participants with type 1 diabetes, opting to fast during Ramadan, were enrolled. Pre-Ramadan, all received specialized education and training for Freestyle Libre (FSL) sensor use. Participants utilized the sensor for 6 weeks (pre-Ramadan and during Ramadan). Physical and biological parameters were collected 2 to 4 weeks before and after Ramadan.

Results: Among the 24 patients on basal bolus insulin and 2 on insulin pumps with FSL data, the average fasting period was 24 days. Ninety-five percent reported educational session benefits. No clinically significant changes in physical/biological data occurred pre/post-Ramadan, except for a reduction in HbA1c from 8.2% to 7.9% post-Ramadan ($P=0.010$). While 63% adjusted insulin doses during Ramadan, flash glucose monitoring revealed fewer hypoglycemic episodes (29.2% vs. 46.7% pre-Ramadan). One case of diabetic ketoacidosis occurred due to missed insulin doses to prevent hypoglycemia.

Conclusion: Selective individuals with type 1 diabetes, receiving optimal care, demonstrated improved glycemic control and reduced hypoglycemia risk during Ramadan fasting. Larger, randomized controlled trials are necessary for generalizing these findings as recommendations.

Keywords: Ramadan fasting, Type 1 Diabetes Mellitus, glycemic control.

Introduction:

Managing diabetes during Ramadan presents a significant challenge for healthcare providers and patients globally. With an estimated 1.8 billion Muslims worldwide, fasting during Ramadan is obligatory for adult and adolescent Muslims, involving abstaining from food and drink between dawn and sunset. Despite exemptions for those with chronic illnesses or poor health, many patients with diabetes are eager to fast, defying medical advice and religious exemptions. (El Toony et al., 2018)

Current recommendations from the International Diabetes Federation (IDF) and Diabetes and Ramadan (DAR) Alliance Group classify patients with type 1 diabetes mellitus as high to very high risk for fasting and advise against it. Risks include hypoglycemia, hyperglycemia, dehydration, and diabetic ketoacidosis. Nonetheless, a considerable proportion of patients opt to fast. In the EPIDIAR study, 42.8% of 1,070 type 1 diabetes patients across 13 countries were willing and able to fast for at least 15 days during Ramadan. (Fokkert et al., 2017)

Managing type 1 diabetes poses challenges in avoiding glycemic extremes, especially during fasting when prolonged daytime fasting is followed by carbohydrate and sugar-rich evening meals. Continuous glucose monitoring (CGM) has emerged as a valuable tool for monitoring blood glucose non-invasively and adjusting insulin and diet based on glucose readings, thus reducing glycemic variability. (Petrie et al., 2017)

Recent studies have examined glycemic control during Ramadan fasting, primarily focusing on children and adolescents. Questions arise regarding the safety of fasting in type 1 diabetes, particularly regarding insulin regimen types and dose adjustments to mitigate hypoglycemia and hyperglycemia. While some studies found no major differences between continuous subcutaneous insulin infusion (CSII) and multiple daily injections (MDI), others found less glycemic variability with CSII. Insulin reduction, particularly in long-acting insulin, did not consistently reduce hypoglycemia rates. (Mohamed et al., 2019)

Studies utilizing CGM or flash glucose monitoring reported low rates of severe hypoglycemia and diabetic ketoacidosis during Ramadan but frequent asymptomatic hypoglycemia, particularly during fasting hours. While most trials focused on hypoglycemia rates within Ramadan, few compared rates pre and post-Ramadan, with mixed results. (Tourkmani et al., 2016)

Despite the inconsistent impact of CGM technology on glycemic control and hypoglycemia reduction, studies underscore the positive role of education in managing diabetes during Ramadan. (Afandi et al., 2018)

Methodology:

Subjects and Procedure:

This prospective interventional, single-center trial aimed to assess the safety of fasting among patients with type 1 diabetes mellitus during Ramadan. Participants aged 14-75 with a confirmed diagnosis of type 1 diabetes were included. Patients were advised against fasting per guidelines, but those who insisted were offered enrollment. Participants were selected conveniently 1 to 2 months before Ramadan, provided counseling, and signed informed consent. Exclusion criteria included type 2 diabetes, concurrent renal or ischemic heart disease, pregnancy, or recent hospitalization within the preceding 3 months. All participants received a 60-minute Ramadan-focused educational session (DAR SaFa) covering lifestyle modifications, treatment adjustments, indications for breaking fast, and dietary/fluid intake advice. Freestyle Libre flash sensor insertion for continuous glucose monitoring was performed after consent, and patients were instructed on its use. Physical and biological data were collected 2 to 4 weeks before and after Ramadan, including diabetes-related emergency visits or hospitalizations, weight changes, blood pressure, lipid profile, renal function, HbA1c, and urine microalbumin/creatinine ratio.

Data Collection and Analysis:

Data were entered into Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 23. Paired Student's t-tests assessed differences in continuous variables between baseline

and various time points. Independent t-tests, ANOVA, and Chi-square tests evaluated differences between groups. Results were considered statistically significant at $P \leq 0.05$.

Results:

Data Sources and Fasting Ability:

A total of 30 patients with type 1 diabetes were initially recruited. Four patients dropped out during the pre-Ramadan phase, with one due to hospitalization for diabetic ketoacidosis early in Ramadan, and two due to incomplete protocol adherence. Therefore, 24 patients with continuous glucose monitoring (CGM) data were included. The majority utilized basal bolus insulin (n=22), with two patients on insulin pumps. Twenty-one percent fasted the entire month of Ramadan, with an average fasting duration of 24 days. Ninety-five percent reported satisfaction with the pre-Ramadan educational session, and 63% made insulin dose adjustments during Ramadan.

Clinical and Metabolic Parameters:

Mean weight, systolic and diastolic blood pressure showed no statistically significant changes pre and post-Ramadan.

Glycemic Control:

Peak glucose levels were similar before and during Ramadan, with mean average glucose around Iftar time at $181.1 \text{ mg/dl} \pm 58$ and 2 hours later at $231.0 \text{ mg/dl} \pm 66$. HbA1c decreased from 8.23% to 7.89% post-Ramadan, but sensor estimated HbA1c increased from 7.93% to 8.52% during Ramadan.

Safety Profile:

One admission for diabetic ketoacidosis occurred on the first day of Ramadan due to insulin dose omission. No hospital admissions due to hypoglycemia or hyperglycemia were reported.

Hypoglycemic Events:

The frequency and duration of hypoglycemic episodes did not significantly differ before and during Ramadan. However, during Ramadan, fewer patients experienced hypoglycemic episodes compared to non-fasting days, though this difference was not statistically significant. Most hypoglycemic events occurred between 00:00 to 06:00, both before and during Ramadan, with fewer events between 06:00 to 12:00.

Overall, while there were trends towards fewer hypoglycemic episodes during Ramadan, particularly between 00:00 to 06:00, these differences were not statistically significant.

Table 1: Baseline Characteristics of Study Cohort

Characteristics	Values
Total patients recruited	30
Patients with CGM data	24
Insulin regimen	Basal bolus insulin: 22 Insulin pump: 2
Average fasting duration	24 days
Patients fasting entire month of Ramadan	21%
Satisfaction with pre-Ramadan education	95%
Insulin dose adjustments	63%

Table 2: Clinical and Metabolic Parameters

Parameters	Before Ramadan	After Ramadan
Mean weight (kg)	70.16 ± 17.92	69.61 ± 16.70
Systolic BP (mmHg)	116.31 ± 15.45	116.13 ± 12.25
Diastolic BP (mmHg)	69.7 ± 7.46	66.31 ± 10.1
HbA1c	8.23%	7.89%
Sensor estimated HbA1c	7.93%	8.52%

Table 3: Hypoglycemic Events

Parameters	Before Ramadan	During Ramadan
Total patients with CGM data	24	24
Hypoglycemic events < 49 mg/dl	79%	66.7%
Patients with more than 10 episodes	46.7%	29.2%
Patients with no hypoglycemic events	-	Statistically not significant
Most hypoglycemic events (time)	00:00 - 06:00	00:00 - 06:00

Discussion:

Achieving stable glycemic control without major fluctuations leading to severe hypoglycemia, hyperglycemia, or diabetic ketoacidosis is crucial in managing patients with type 1 diabetes mellitus, especially during fasting periods like Ramadan. Despite being classified as high to very high risk for fasting, our study suggests that selective patients with type 1 diabetes without major complications may safely fast during Ramadan with optimal care. (Pew Research Center, 2015)

Our study provided participants with various components of optimal care, including access to a flash glucose sensor and monitor, availability of educators and physicians, regular clinic follow-ups, and Ramadan-focused education. While it's difficult to pinpoint which aspect of care had the most significant impact, non-invasive glucose monitoring proved clinically useful. However, it's worth noting that the use of continuous glucose monitoring (CGM) requires appropriate training and education for its effective utilization. (Abdelgadir et al., 2015)

The importance of education in managing diabetes during Ramadan is evident from previous studies, including ours. Mohamed et al. demonstrated a significant reduction in post-intervention hypoglycemia rates with pre-Ramadan structured education, similar to the DAR-SaFa program used in our study. This highlights the critical role of education in improving fasting safety. (Klonoff et al., 2017)

Despite the availability of optimal care, only 21% of our patients fasted the entire month of Ramadan, indicating the perceived difficulty even among motivated individuals. However, the average fasting duration of 24 days suggests that patients still engaged in fasting for a substantial period, highlighting the importance of balanced decision-making. (Alamoudi et al., 2017)

Comparing our findings to previous studies in patients with type 1 diabetes during Ramadan, we observed a reduction in hypoglycemic episodes during Ramadan. While insulin dose adjustments were reported by many patients, it's unclear whether this alone contributed to the improvement. Studies by Deeb et al. and Alamoudi et al. showed no improvement in hypoglycemia rates with insulin dose reduction or between different insulin regimen types. (Afandi et al., 2018)

Regarding the timing of hypoglycemia, our study showed a lower frequency of episodes prior to breaking the fast, contrasting with findings by Kaplan et al. This discrepancy could be attributed to insulin dose adjustments and access to medical care. Most hypoglycemic events occurred at night, possibly due to inappropriate carbohydrate intake and insulin dosing. (Deeb et al., 2017)

Despite some limitations, such as the observational nature of our study and the lack of detailed data on insulin dose adjustments, it provides valuable insights into glycemic control during Ramadan in adult patients with type 1 diabetes. Further research, ideally in larger randomized controlled trials, is warranted to validate these findings and generalize recommendations for managing type 1 diabetes during Ramadan. (Mohamed et al., 2019)

Conclusion:

The provision of optimal care for selective patients with type 1 diabetes offers the potential for safe fasting during Ramadan, characterized by a low complication rate, reduced hypoglycemia, and stabilized biometric and metabolic parameters. Achieving this requires a comprehensive approach encompassing individualized care, access to flash glucose monitoring, structured education sessions focused on Ramadan and diabetes management, and engagement with specialist diabetes centers.

While our study provides promising insights, further research through larger randomized controlled trials is necessary to validate and generalize these findings into recommendations for managing type 1 diabetes during Ramadan. This will help establish evidence-based guidelines that can optimize the safety and efficacy of fasting for individuals with type 1 diabetes during this religious observance.

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