



Timing of the Final Nocturnal Meal and Hypoglycemia Risk in Fasting Individuals with Type 1 Diabetes: A Randomized Crossover Trial

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Abstract

Background Despite known risks, many individuals with type 1 diabetes (T1D) fast during Ramadan. Local studies have shown that breaking the fast due to hypoglycemia is common during the morning hours; however, the optimal timing of Suhoor (the predawn meal) has not been thoroughly investigated. Current guidelines recommend late Suhoor; however, this does not provide sufficient time for correction in case of insulin overdosing and can lead to breaking the fast in the early hours.

Objective To compare the risk of hypoglycemia in individuals with T1D fasting during Ramadan between an early Suhoor (90–120 minutes before dawn plus a predawn snack) and a late Suhoor (30 minutes before dawn).

Methods In this randomized crossover trial, participants with T1D were assigned to either an early or late Suhoor regimen for 1 week, then switched to the other regimen for the second week. Data were collected via questionnaires and flash continuous glucose monitoring (FCGM).

Results Forty-four patients were enrolled (73.5% female, mean age 25 ± 5.9 years). During early versus late Suhoor, the proportion of individuals who broke their fast due to hypoglycemia was 64.5% versus 58.1% ($p = 0.18$). Most hypoglycemia episodes occurred during early fasting hours. Mean fast-breaking days were similar (2.5 vs. 2.05; $p = 0.7$). FCGM-detected hypoglycemia rates were comparable (5.5 vs. 5.4 events/week; $p = 0.65$), but hypoglycemia was significantly more frequent in the morning/noon than pre-sunset (1.9 vs. 0.43 events; $p < 0.001$). The ambulatory glucose profiles of the early versus late regimens were glucose management indicator: 7.58 ± 1.01 versus 7.49 ± 0.9 ($p = 0.36$), time in range (70–180 mg/dL) of $46.9 \pm 17.3\%$ versus $47.9 \pm 17.3\%$ ($p = 0.99$), time below range (<70 mg/dL) of $8.6 \pm 14.3\%$ versus $7.8 \pm 7.6\%$ ($p = 0.15$), time above range (>180 mg/dL) of $45.8 \pm 22.03\%$ versus $44.5 \pm 20.1\%$ ($p = 0.6$), and glucose variability of $39.3 \pm 10.5\%$ versus $40.6 \pm 6.5\%$ ($p = 0.005$).

Conclusion Adjusting Suhoor timing was well tolerated and offered flexibility. Further research is needed to optimize fasting strategies for individuals with T1D.

Keywords

- Ramadan
- fasting
- early Suhoor
- late Suhoor
- type 1 diabetes

Introduction

Ramadan is the Muslim holy month of fasting, where Muslims abstain from food and drink from dawn to sunset. Patients with type 1 diabetes (T1D) are considered at high risk for complications related to fasting and are generally advised not to fast.¹ Despite the high risk, many T1D patients choose to fast during Ramadan,² and their health care providers are faced with the challenge of managing their diabetes while fasting.

Suhoor is the last meal taken before the fast begins. To reduce fasting hours and maintain glycogen stores, current guidelines recommend delaying Suhoor as late as possible.¹ However, a recurring issue reported by some patients³ is that this does not leave sufficient time for correcting an over- or under-estimated insulin dose, leading to an early need to break the fast to correct blood glucose levels.

Studies have shown that in Saudi Arabia, breaking the fast due to hypoglycemia is common during the morning hours^{4–6}; however, the optimal timing of Suhoor (predawn meal) has not been investigated. We suggest an approach that allows more time for predawn blood glucose correction, in which the main Suhoor meal is consumed 90 to 120 minutes before dawn, accompanied by an insulin dose, and a high-protein snack without insulin is consumed just before dawn. This regimen ensures that blood glucose levels are within range before starting the fast while maintaining adequate glycogen stores.

Patients and Methods

Study Design

A randomized crossover trial was conducted at King Abdulaziz Medical City—National Guard Ministry of Health Affairs during the fasting month of Ramadan (April 12, 2021–May 12, 2021). Participants were recruited from a single tertiary hospital population. They were included if they had been diagnosed with T1D for more than 6 months, were aged >14 years, committed to performing self-monitoring blood glucose (SMBG) measurements or were on continuous glucose monitoring (CGM), multiple daily injections (MDIs), or an insulin pump, had previously fasted during Ramadan and planned to fast during the upcoming Ramadan, and were well educated about the requirements for fasting. Patients with cognitive impairment or learning disability, renal or hepatic impairment, adrenal insufficiency, pregnancy, alcohol use, or a diagnosis of psychiatric disease were excluded from the study.

Recruited patients were randomly assigned in a 1:1 ratio to one of the two groups: early Suhoor and late Suhoor. Each arm consisted of a sequence of two regimens over 2 weeks. The study was a parallel-group, open-label, adaptive, two-group, randomized clinical trial designed to evaluate the regimen most associated with the lowest rate of hypoglycemia among fasting patients with T1D.

Procedures

Patients were randomized to either an early or late regimen and began a diet plan immediately upon study initiation. In the second week, patients switched regimens, following the

crossover design of the study. Measurements were performed by the patients using SMBG with the Freestyle Libre System to monitor their blood sugar levels six to seven times a day during Ramadan: pre-iftar and 2 hours post-iftar (sunset meal), Suhoor meals, and midway between meals, as well as once or twice during the day. The patients were instructed to break their fast when their blood sugar level was less than 70 mg/dL or more than 300 mg/dL. Patients accustomed to adjusting their insulin dose based on home glucose monitoring results were allowed to do so. No standardized insulin titration protocol was implemented as part of the trial; adjustments were performed according to each participant's usual practice, in line with the general Ramadan diabetes education they had previously received. At enrollment, baseline demographic information, including age, gender, and type and duration of diabetes, was collected. Post-Ramadan data were then collected via a patient survey.

Outcomes and Independent Variables

The primary outcome was the incident rate of hypoglycemic events during the study period, specifically during early (90–120 minutes before dawn and predawn snack) and late (30 minutes before dawn) Suhoor regimens in fasting T1D patients during Ramadan. The secondary outcomes included the comparison of other measured variables, including the number of days on which the fast was broken, parameters of blood glucose control as per the ambulatory glucose profile (AGP) report (mean blood glucose, mean fasting blood glucose, mean 2-hour post-prandial blood glucose, mean glucose management indicator, mean glucose variability, mean time in range [TIR], time above range [TAR], and time below range [TBR]), and patient preferences between both groups.

Statistical Analysis

Primary and secondary analyses were performed for all participants based on their randomized intervention. SAS statistical software and the PLAN procedure for patient randomization were used. In the univariate unadjusted analysis, descriptive statistics are expressed as mean $\pm$ standard deviation or percentage using the chi-square test or Fisher's exact test, as appropriate. In the multivariate analysis, a general linear model (GLM) with repeated measures analysis was used to compare blood sugar measurements at each measurement time during the study period. Two interaction terms were also included in the model to evaluate the differences in blood sugar measurements between the regimen groups and measurement times throughout the day. In the secondary analyses, we used the GLM to further estimate the differences between the two regimens regarding the number of days patients needed to break their fast, daytime hyperglycemia, the rate of severe hyperglycemia, and glucose variability. Multiple logistic regression analysis was used to evaluate the results of the patient preferences survey. Assumptions of a linear function, including the independent coefficients, error, and assumptions of normality and homogeneity of variance components, were examined.⁷ A p -value <0.05 was considered statistically significant for the multivariate analyses. All statistical analyses were performed using SAS 9.4 software.

Results

A total of 44 patients with T1D were randomized in a crossover design to early or late Suhoor regimens for the first week, then crossed over to the other regimen for the second week. The mean age of the participants was 25 ± 5.9 years, with a mean duration of diabetes of 13 ± 6.7 years. Except for two patients on insulin pumps, all patients were on multidose analog injection therapy, with only 31.8% applying carbohydrate counting. All patients reported regular SMBG, and 30.2% had an HbA1c level at the target of $<7\%$ (53 mmol/mol). At baseline (pre-Ramadan), 10 patients reported experiencing frequent hypoglycemia (more than 3 episodes/week), and 4 reported a history of hypoglycemia unawareness. Furthermore, 88.6% met the high-risk criteria for fasting according to the Diabetes and Ramadan (DAR) guidelines² (► **Table 1**). In total, 38 patients completed both randomization phases. Breaking the fast was reported by 20 (64.55%) and 18 (58.1%) participants, respectively, during regimen use ($p = 0.16$), with a mean number of fast days broken of 2.5 ± 1.6 versus 2.05 ± 1.4 days, respectively ($p = 0.72$). There was one episode of severe hypoglycemia reported during the late regimen, and no diabetic ketoacidosis admissions were reported during either regimen. Breaking the fast due to hypoglycemia was more frequently reported during the morning and early noon hours than pre-sunset (► **Fig. 1**). Hypoglycemic events, as detected by FCGM, occurred significantly more frequently during the morning and early hours of fasting than in the evening; however, there was no significant difference between regimens (► **Fig. 2**). The mean hypoglycemia event rate per patient per week during the early versus late regimen was 0.83 compared to 0.78 events/patient/weeks ($p = 0.31$). Hypoglycemic events were significantly more frequently reported during the morning/noon compared with pre-sunset in both regimens, with 4.1 events versus 1.4 events, respectively ($p = 0.003$). The AGP report data revealed a longer average duration of hypoglycemia while on the late regimen (146.1 ± 102.5) compared with the early regimen (106.6 ± 89.8) ($p = 0.04$). There was a high prevalence of poor glycemic control; the TAR and TBR were above target during both regimens, with no statistically significant difference (► **Fig. 3** and ► **Table 2**). The post-Ramadan satisfaction survey revealed that both regimens were generally acceptable, with a greater preference for the late regimen due to its convenience in timing and ease of adaptation (► **Fig. 4**).

Discussion

In this randomized, crossover trial, we aimed to assess and compare the safety of two regimens for Suhoor meal intake in patients with T1D who fasted during Ramadan. Regimen 1 consisted of having Suhoor 90 to 120 minutes before the start of fasting with an insulin dose and a low-carbohydrate, high-protein snack just before fasting without insulin administration, while regimen 2 consisted of having the Suhoor meal with insulin administration 15 to 30 minutes before the start of fasting, which is in line with the current standard of care

Table 1 Demographics and baseline characteristics

Variables	Results ^a
Age (y)	25 ± 5.9
Sex:	
Male	13 (29.5%)
Female	31 (70.5%)
Duration of diabetes	13.0 ± 6.7
Baseline HbA1c distribution^b:	
$<7\%$	13 (30.2)
7–9%	21 (48.8)
$>9\%$	9 (21)
Type of insulin:	
Multiple-dose injections	42
Insulin pump	2
Daily insulin dose (units):	
Basal	28.1 ± 12.9
Prandial	33.9 ± 14.1
Applies Carb counting (Yes):	14 (31.8%)
History of frequent hypoglycemia ^c	10 (22.7%)
Hypoglycemia unawareness:	4 (9.1%)
Complications:	
No complications	38 (86.4%)
Retinopathy	5 (11.4%)
Nephropathy	1 (2.3%)
Physical activity:	
Active	12 (27.2%)
Mildly active	18 (40.9%)
Not active	14 (31.8%)
Frequency of SMBG monitoring/day:	
Four times per day	41 (93.1%)
>4 times per day	1 (6.9%)
DaR risk category:	
High	39 (88.6%)
Moderate	5 (11.4%)

Abbreviation: SMBG, self-monitoring blood glucose.

^aResults are presented as mean $\pm$ standard deviation for continuous variables and number (percent) for categorical variables.

^bOne missing datapoint.

^c >3 hypoglycemic episodes/week.

clinical practice guidelines.² Studies have shown that patients with T1D follow different dietary patterns and routines for the timing of insulin injections during Ramadan⁸; these attitudes and behaviors could significantly affect blood glucose levels during fasting. The emphasis in clinical guidelines to date has been on insulin dose reduction rather than modifying meal timing and distribution.^{9–15} Notably, recent studies have highlighted the importance of structured, localized approaches to managing T1D during

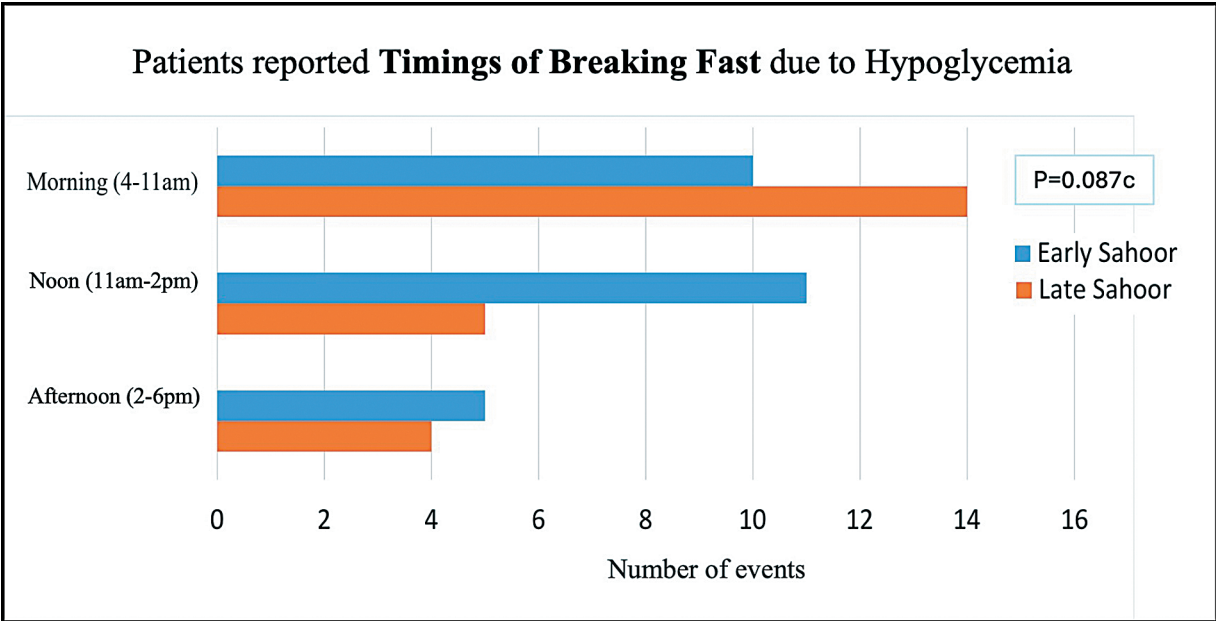


Fig. 1 Patients reported timings of breaking fast due to hypoglycemia.

Ramadan, supporting the need for individualized, evidence-based strategies.^{16,17} To the best of our knowledge, the timing of Suhoor, its relation to hypoglycemia, and its effect on the outcome of fasting have not been studied. Our study

suggests that the early Suhoor regimen was well tolerated, with no significant difference in hypoglycemia risk or in the mean number of days on which the fast was broken between the regimens.

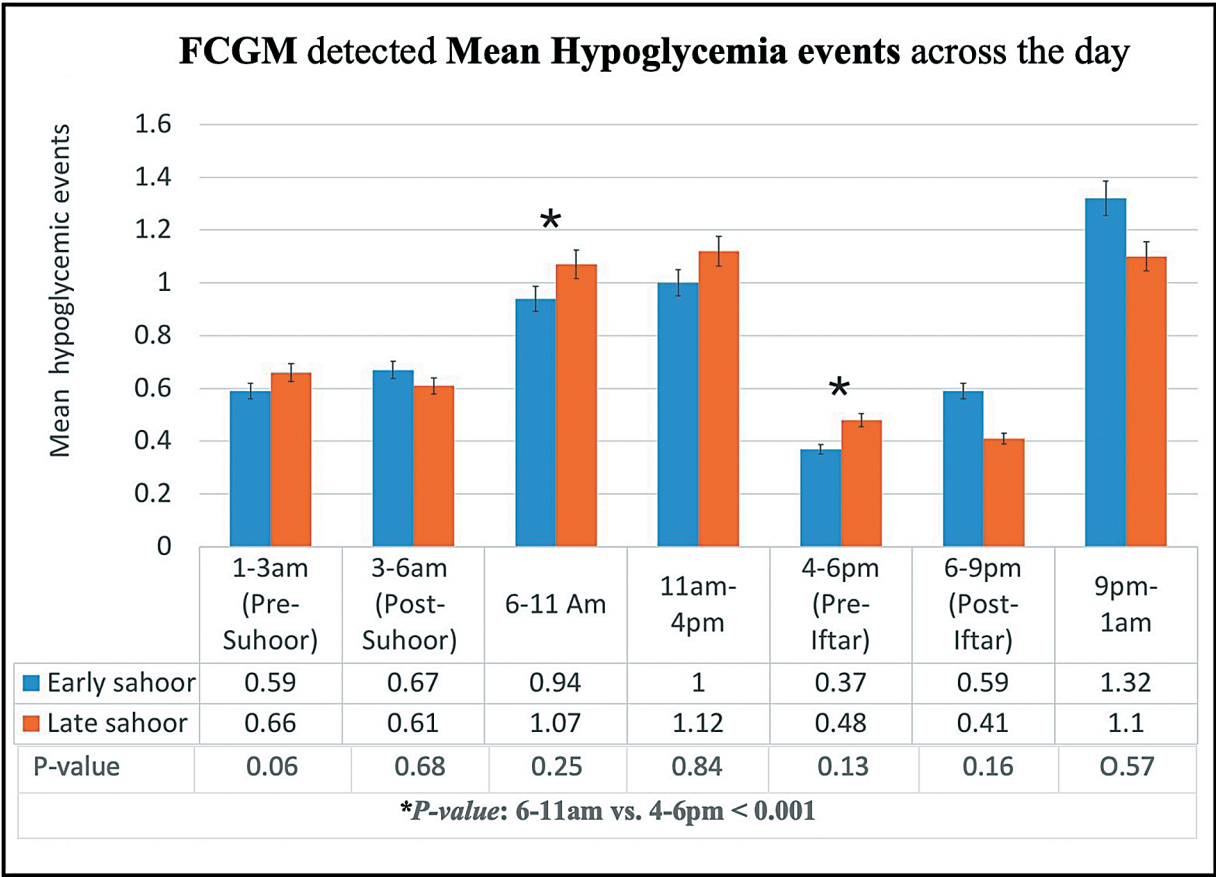


Fig. 2 Flash continuous glucose monitoring glucose-detected mean hypoglycemia events across the day.

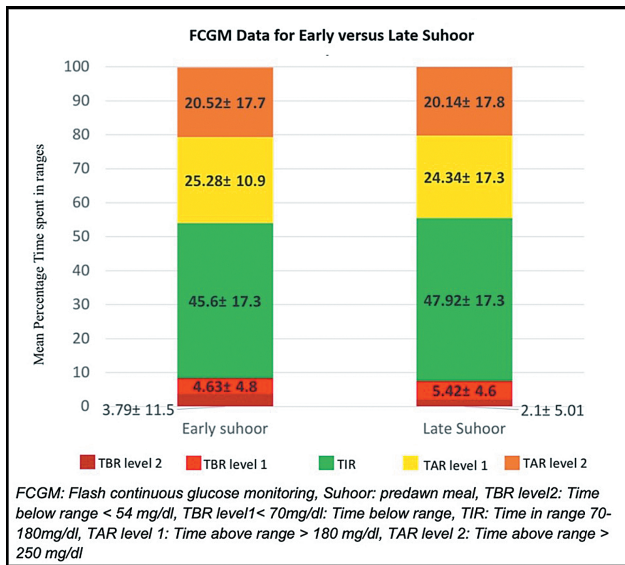


Fig. 3 Flash continuous glucose monitoring glucose report data early versus late Suhoor.

Understanding the timing of hypoglycemia in relation to fasting is crucial for guiding insulin dose adjustment during fasting. An important observation in our study was the significantly higher prevalence of hypoglycemic events during the early fasting hours (morning and noon) compared with pre-sunset hours in both regimens; these findings contrast with those of other studies¹⁶ but are consistent with previous studies in Saudi Arabia.^{4–6,19} This suggests that the Suhoor meal insulin dose has a greater impact on hypoglycemic events requiring rapid correction in the Saudi population than basal insulin. Variation in the timing of hypoglycemic events may be linked to several factors, including insulin dosage, fasting duration, physical activity during fasting hours, and other independent variables. Reliance on insulin dose reduction alone is insufficient to avoid hypoglycemic events during fasting. Using FCGM has been shown to benefit T1D patients during fasting.^{17–19} In the present study, we utilized FCGM to identify hypoglycemic events¹⁴ and monitor blood glucose levels during both regimens. A high prevalence of poor glycemic control during fasting was noted, which was not affected by the treatment regimen, with 47.02% (early) and 47.27% (late) TIR. However, glucose variability and time spent in hypoglycemia were

improved in the early regimen compared with the late regimen.

Nevertheless, by the end of the trial, more patients expressed a preference for the late Suhoor timing. The main reason was convenience, as late Suhoor aligns with established family and cultural routines during Ramadan. This highlights that patient preference, strongly influenced by lifestyle feasibility, is an important factor to consider when providing education and support.

Optimal pre-Ramadan glycemic control can reduce the potential risks associated with fasting by minimizing glucose fluctuations.¹⁸ The T1D patients included in this trial were mostly on MDI; however, only 31.8% were applying carbohydrate counting, and one-third (30.2%) had a HbA1c at target before Ramadan. Moreover, 88.6% of our patients met the high-risk criteria for risk stratification according to the DAR guidelines, but insisted on fasting. Fasting against medical advice is common among T1D patients²⁰ and represents a challenge for their managing medical team. There are limited data regarding the incidence of complications in fasting high-risk diabetic patients during Ramadan; however, a systematic review reported a minimal increase in the incidence of complications during Ramadan compared with other times of the year, despite proper education and self-titration.²¹ No major complications were reported in our study, and fasting was well tolerated during both regimens.

Our study was limited by its small sample size and single-center design. Furthermore, it was not possible to determine the impact of insulin titration due to the absence of data on the daily insulin dose adjustments made by patients. Additionally, the use of FCGM instead of real-time CGM may have affected the accuracy of the reported hypoglycemia. Other limitations include variability in individual responses to fasting, reliance on self-reported adherence to meal timing, and the potential influence of unmeasured confounding factors such as differences in physical activity or sleep patterns during Ramadan. Nevertheless, the crossover randomized design effectively doubled the sample size and removed inter-subject variability, thereby strengthening the study findings. To the best of our knowledge, this is the first study to examine the effect of mealtime modification on the safety of fasting in patients with T1D using a randomized design. In practice, many individuals may have different patterns for Suhoor consumption or may skip it entirely; these scenarios warrant further study.

Table 2 Comparison of FCGM report data: early vs. late Suhoor regimens

Variables	Early Suhoor	Late Suhoor	p-Value
Number of patients	38	38	–
Average glucose (mg/dL)	182.5 ± 49.9	180.1 ± 43.6	0.42
Glucose management indicator (%)	7.58 ± 1.01	7.49 ± 0.9	0.39
Glucose variability (%)	39.3 ± 10.5%	40.6 ± 6.5%	0.005
Average duration of hypoglycemia (min)	106.6 ± 89.8	146.1 ± 102.5	0.04

Abbreviation: FCGM, flash continuous glucose monitoring.

Note: Results are shown as mean ± SD. Suhoor: predawn meal.

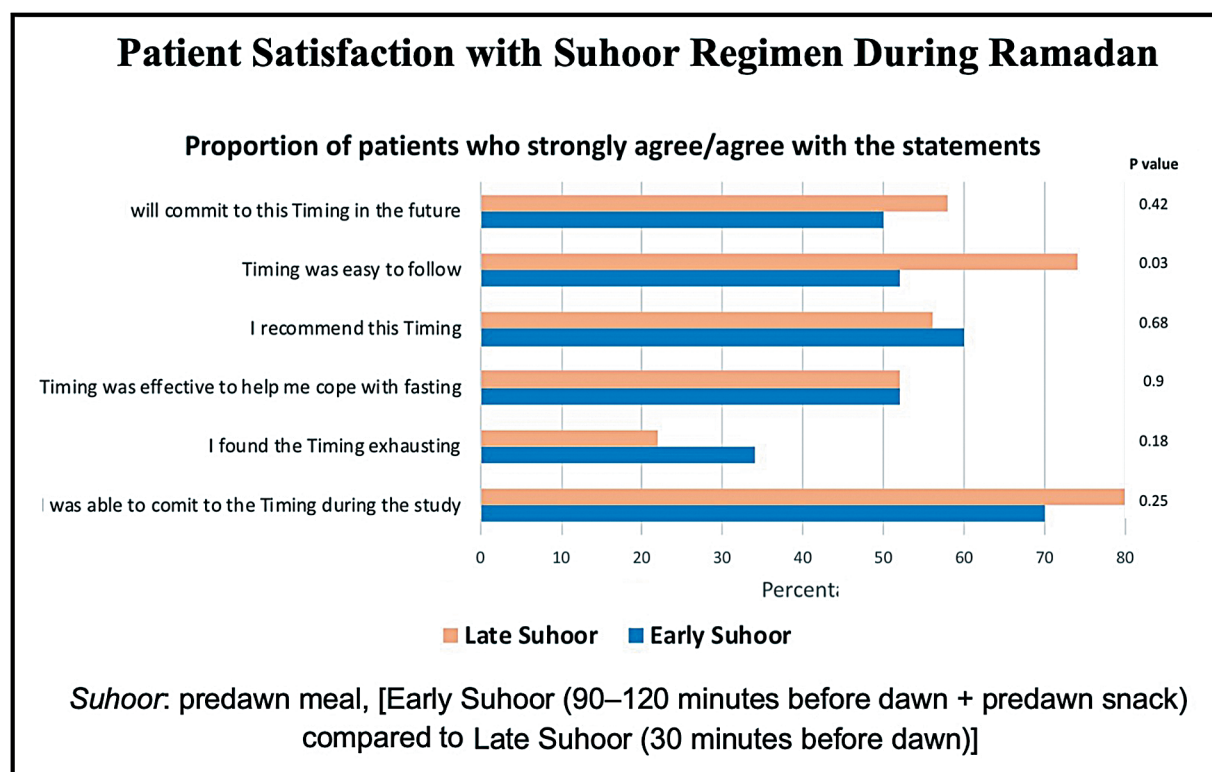


Fig. 4 Patient satisfaction with the Suhoor regimen during Ramadan.

Conclusion

Both Suhoor regimens produced minor variability and were tolerated sufficiently. Both regimens can be followed according to patients' preferences to minimize complications and improve the fasting experience for patients with T1D. Further studies are needed to investigate various dietary and insulin dosing regimens to ensure safe fasting in patients with T1D.

Author Contribution

All named authors participated in the conception, planning, and conduct of the study; drafting and revision of the manuscript; and approval of its final version.

Compliance with Ethical Principles

The trial protocol was approved by the Research Office of King Abdulaziz International Medical Research Center (IRBC/0517/21). All participants provided written informed consent. ClinicalTrials.gov: NCT04864483.

Funding and Sponsorship

None.

Conflict of Interest

None declared.

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