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Effect of Whey Protein Consumption on Hypoglycemia Risk in Patients with Type 1 Diabetes Fasting during Ramadan: A Randomized, Crossover Trial

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Abstract

Background Fasting during Ramadan presents challenges for people with type 1 diabetes (T1D), particularly regarding hypoglycemia risk. Nutritional strategies such as whey protein (WP) supplementation may support safer fasting.

Objective This article assesses the effect of WP supplementation at the predawn meal (*Suhoor*) on hypoglycemia risk and fasting continuity among patients with T1D during Ramadan fasting.

Methods In this randomized, controlled, crossover trial, individuals with T1D planning to fast during Ramadan were recruited and assigned to two study phases: one with WP supplementation at *Suhoor* and one without. Outcomes were assessed using continuous glucose monitoring (CGM), dietary logs, and pre- and post-Ramadan questionnaires. The primary outcomes were the number of hypoglycemic events and the days fasting was interrupted.

Results Forty-one patients with T1D were randomized; 33 were on multiple daily injections and 8 on continuous subcutaneous insulin infusion. The mean age was 24 ± 4.2 years, with a mean diabetes duration of 14.1 ± 7.3 years; 22 participants (53.7%) were female. Pre-Ramadan glycated hemoglobin was 7.6 ± 1.07%. At baseline, 5 patients (12.2%) were categorized as moderate risk by the DaR (Diabetes and Ramadan Alliance) risk score, and 36 (87.8%) as high risk. WP supplementation was associated with a significant reduction in the number of days on which the fast was broken (0.94 ± 1.25 vs. 1.15 ± 1.33 days; $p = 0.008$). The timing of reported interruptions of the fast due to hypoglycemia was similar across both weeks, with most occurring during the morning hours. CGM-detected mean hypoglycemia events per patient per week by time of day were 0.7 versus 1.1 post-Suhoor (3–6 a.m.) and 0.3 versus 0.6 pre-Iftar (4–6 p.m.), with $p = 0.07$ and $p = 0.05$, respectively. However,

Keywords
- Ramadan fasting
- type 1 diabetes
- hypoglycemia
- whey protein
- continuous glucose monitoring

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overall CGM-detected low events and ambulatory glucose profile metrics (time in range, time below range, glucose management indicator, and glucose variability) did not differ significantly between the two regimens. No severe hypoglycemia, diabetic ketoacidosis, or hospital admissions were reported in either week. In the poststudy survey, 51.2% of participants reported that WP at Suhoor was beneficial, and 68.3% indicated that they would use it again during Ramadan fasting.

Conclusion WP supplementation at Suhoor may reduce hypoglycemia-related fast-breaking in adults with T1D during Ramadan without compromising glycemic safety. These findings support WP as a feasible adjunct to structured fasting plans in T1D. Further, larger multicenter studies are needed.

Introduction

Fasting during Ramadan is observed by millions of Muslims worldwide, including those with chronic conditions such as diabetes. Patients with type 1 diabetes mellitus (T1D) face unique challenges during fasting hours, notably the risk of hypoglycemia, hyperglycemia, and diabetic ketoacidosis (DKA).[1–3] Despite these risks, many patients choose to fast,[4,5] and thus, safe and individualized strategies to support fasting are needed.

Whey protein (WP) has been shown to moderate postprandial glucose excursions by stimulating insulin secretion, increasing glucagon-like peptide-1 (GLP-1) release, and delaying gastric emptying.[6–9] These physiological effects have been observed in both healthy individuals and those with diabetes. However, most existing studies have been conducted in the context of type 2 diabetes (T2D) or postprandial glucose control in nonfasting individuals.[6–10] Emerging data in individuals with T1D suggest that WP may also reduce the risk of hypoglycemia in high-vulnerability settings, supporting its potential role in mitigating hypoglycemia during real-life scenarios, such as postexercise or fasting periods.[11,12]

The coingestion of protein with carbohydrate-containing meals improves glycemic profiles by slowing glucose absorption and promoting insulinotropic and incretin responses.[6–8] This effect may be particularly useful during the predawn meal (*Suhoor*) in Ramadan, as it helps reduce the risk of early morning hypoglycemia.[13,14] This study aims to evaluate whether consuming WP at *Suhoor* reduces the risk of hypoglycemia among individuals with T1D who fast during Ramadan. This is the first randomized, crossover trial to evaluate WP supplementation at *Suhoor* in this population.

Patients and Methods

Study Design and Setting

A randomized, controlled, crossover trial was conducted at the Diabetes Centre of King Abdulaziz Medical City in Jeddah, Saudi Arabia.

Patients were included if they had been diagnosed with T1D for more than 6 months, were aged 14 years or older, and were on continuous glucose monitoring (CGM) or multiple daily injections (MDIs). They were well-informed about fasting requirements and were willing to comply with the study instructions. 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.

Intervention

Each participant completed two 1-week intervention periods during Ramadan: one with WP supplementation at *Suhoor* and one without. Structured dietary education was provided by a dietitian prior to the intervention. During the supplementation period, participants consumed a WP shake in addition to their usual *Suhoor* meal. The shake consisted of one scoop of WP powder (containing 24 g of protein per scoop) mixed with 200 mL of low-fat milk (~6 g of protein), providing a total of approximately 30 g of protein per serving. Both the protein supplement and the milk were provided to participants. The supplement was consumed with the Suhoor meal alongside prandial insulin. While the WP supplement and milk were standardized, the remaining Suhoor meal composition was not controlled. Participants maintained a dietary diary throughout both periods, documenting the components of Suhoor meals, the timing of intake, insulin dosage, pre- and post-*Suhoor* blood glucose levels, and the method of WP preparation. Daily food logs, flash CGM (Freestyle Libre), and pre- and post-Ramadan questionnaires were also used to assess outcomes. No washout period was included between the two intervention weeks; the risk of carryover effects was considered minimal given the short half-life of WP.

Outcomes

The primary outcome was the incidence rate of hypoglycemic events and time spent in hypoglycemia during the study period. 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 postprandial blood glucose, mean glucose management indicator [GMI], mean glucose variability, mean time in range, time above range, and time below range), and patient preferences.

Statistical Analysis

Analysis was conducted in accordance with the study objectives. Descriptive statistics were summarized as mean ±

standard deviation (SD) for continuous variables, and as counts and percentages for categorical variables. Data were analyzed using IBM SPSS Statistics, version 20.0 (IBM Corp., Armonk, New York, United States). The distribution of continuous variables was assessed using the Shapiro–Wilk test. Where appropriate, nonnormally distributed data were log-transformed and reassessed for normality. If the transformation failed to achieve normality, nonparametric tests were applied.

For inferential analyses, paired-samples *t*-tests were used to compare pre- and postintervention means for normally distributed variables. At the same time, Wilcoxon signed-rank tests were applied to nonnormally distributed data. Statistical significance was defined as a two-sided α of 0.05. Results were presented using appropriate tables and bar graphs. Treatment effects were expressed as absolute percentage-point differences in time spent within specified glycemic ranges. Continuous data are reported as mean ± SD unless otherwise stated.

Results

Demographic and Clinical Characteristics

A total of 41 participants completed the study (53.7% female), with a mean age of 24 ± 4.2 years and an average diabetes duration of 14.1 ± 7.3 years. Most participants were on MDIs (80.5%), while 19.5% used insulin pumps. 36.6% had well-controlled baseline glycated hemoglobin levels (< 7%), and 87.8% were in the high-risk category according to the DaR (Diabetes and Ramadan Alliance) risk score (►**Table 1**).

Table 1 Baseline demographic and clinical characteristics, treatments, and lifestyle behaviors

Total number of patients	41
Age, y (mean ± SD), range	24 ± 4.19 (18–32)
Sex *n* (%)	
• Male	19 (46.3)
• Female	22 (53.7)
Duration of diabetes (mean ± SD)	14.1 ± 7.30
Occupation, *n* (%)	
Student	22 (53.7)
Employee	11 (26.8)
Others	8 (19.5)
Physical activity, *n* (%)	
• Active	13 (31.7)
• Mildly active	18 (43.9)
Not active	10 (24.4)
Baseline HbA1c (mean ± SD)	7.6 ± 1.07
< 7, *n* (%)	15 (36.6)
7–9	23 (56.1)
> 9	3 (7.3)
Type of insulin (*n*)	33 MDI, 8 pumps
Total insulin dose (mean ± SD)	
Basal	26.3 ± 11.35
Prandial	32.0 ± 17.35
Applies carb counting, *n* (%)	18 (43.9)
History of frequent hypoglycemia	
(≤ 3/week), *n* (%)	20 (66.7)
(≥ 4/week), *n* (%)	10 (22.7)
Complications, *n* (%)	
• No complications	36 (87.8)
• Retinopathy	2 (4.9)
• Nephropathy	3 (7.3)
CGM scan per day (mean ± SD)	10 ± 6.59
DaR risk category, *n* (%)	
• High	36 (87.8)
• Moderate	5 (12.2)

Abbreviations: CGM, continuous glucose monitoring; DaR, Diabetes and Ramadan Alliance; HbA1c, glycated hemoglobin; SD, standard deviation.
Note: Complications and monitoring practices.

Fasting Outcomes

During the 2-week crossover period, 33 participants (80.5%) broke their fast at least once. The primary reasons for fast-breaking were hypoglycemia (93.9%) and hyperglycemia (21.2%). The number of participants who broke fast ≥ 1 day was 15 (45.5%) during the WP week, compared with 18 (54.5%) during the no-WP week ($p = 0.623$). The mean number of days participants broke their fast was significantly lower during the WP week (0.94 ± 1.25) compared with the no-WP week (1.15 ± 1.33, $p = 0.008$; Wilcoxon signed-rank test). The timing of hypoglycemic events was similar across groups, with the majority occurring during the morning hours (56.2% WP vs. 57.9% no-WP); however, these differences were not statistically significant ($p = 0.837$, chi-square test) (►**Fig. 1**). No severe hypoglycemia, DKA, or emergency room visits were reported during either week.

CGM Metrics

Hypoglycemic events detected by CGM occurred significantly more frequently during the post-Suhoor period compared with the pre-Iftar period in both study weeks; however, there was no significant difference between the two regimens (►**Fig. 2**). The mean rate of hypoglycemic events per patient per week did not differ significantly between the WP and no-WP weeks (0.74 vs. 0.73 events; 95% confidence interval, –0.12 to 0.21; $p = 0.885$).

When analyzed by time of day, the mean number of CGM-detected hypoglycemic events per patient per week during the WP versus no-WP week was 0.7 versus 1.1 ($p = 0.07$) for the post-*Suhoor* period (3–6 a.m.) and 0.3 versus 0.6 ($p = 0.05$) for the pre-*Iftar* period (4–6 p.m.) (►**Fig. 2**).

No statistically significant differences were observed between the 2 weeks in terms of average glucose, GMI, glucose variability, or time spent in hypoglycemia (►**Table 2**, ►**Fig. 3**). AGP-derived glycemic profiles across the 24 hours were also comparable between the two regimens (►**Fig. 4**).

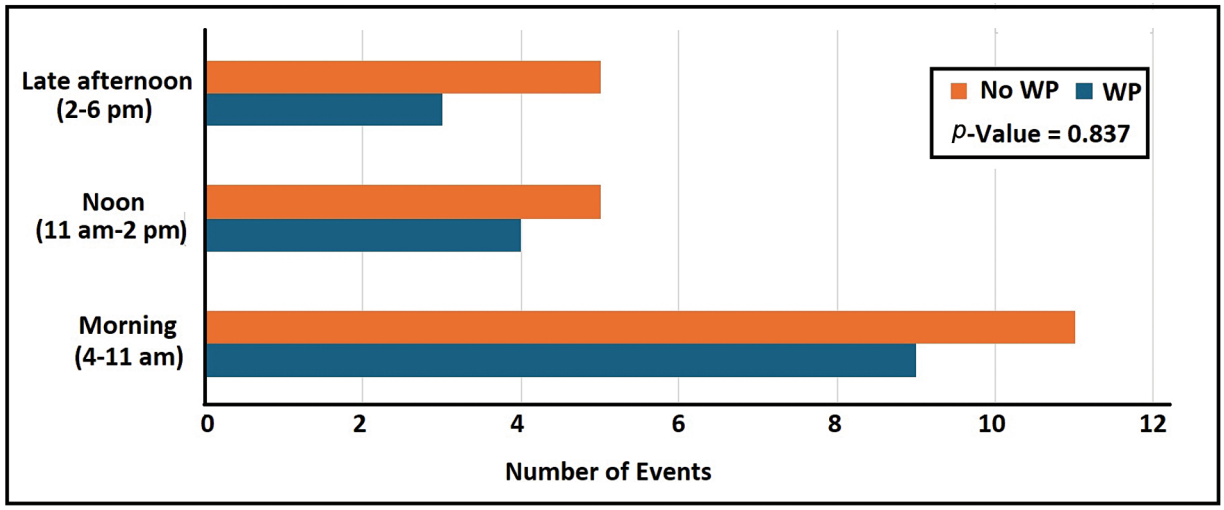

Fig. 1 Comparison of patient-reported timing of breaking fast during whey protein (WP) supplementation week versus non-WP supplementation week.

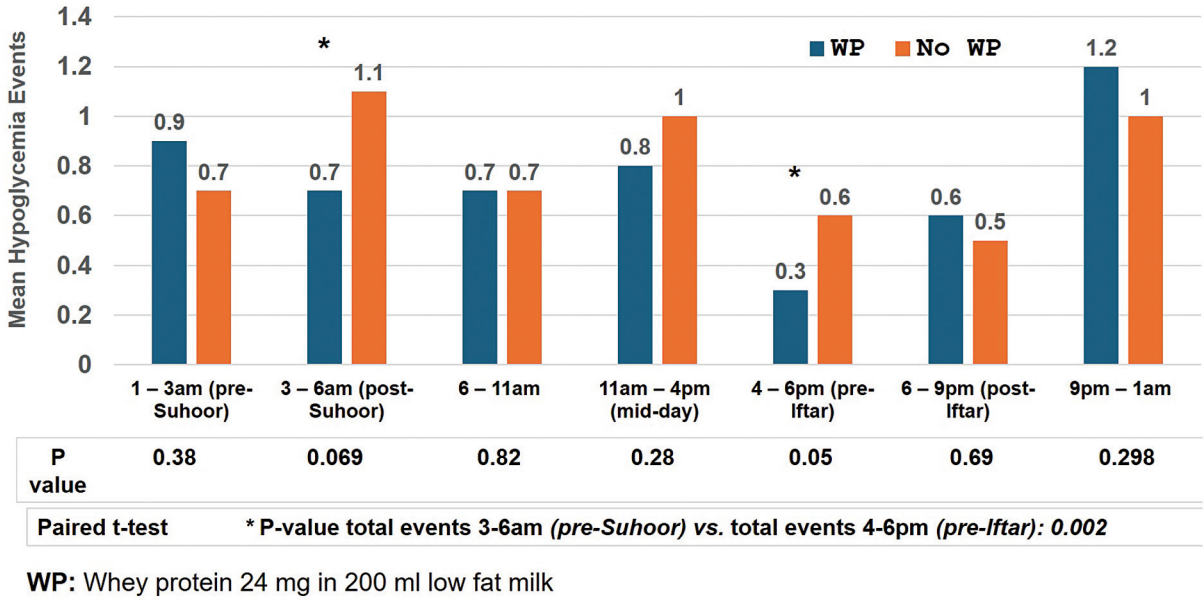

Fig. 2 Comparison of mean hypoglycemic events across the day as detected by continuous glucose monitoring (CGM) during whey protein (WP) supplementation week versus non-WP supplementation.

Table 2 Comparison of AGP report metrics during the WP supplementation week versus the non-WP supplementation week

Characteristics	WP	No-WP	*p*-Value
Number	41	41	
Average glucose (mean ± SD)	184.6 ± 35.4	179.4 ± 35.3	0.23
GMI (mean ± SD)	7.5 ± 1.5	7.4 ± 1.5	0.74
Glucose variability (mean ± SD)	39.8 ± 8.0%	40.8 ± 8.0%	0.33
Average duration of hypos (min) (mean ± SD)	91.2 ± 59.5	97.2 ± 51.4	0.46

Abbreviations: AGP, ambulatory glucose profile; GMI, glucose management indicator; SD, standard deviation; WP, whey protein 24 mg in 200 mL low fat milk.

Patient Acceptability

The post-Ramadan satisfaction survey revealed that 51.2% of participants found the protein supplement beneficial, and 68.3% reported that they would be willing to use it again during Ramadan.

Discussion

Our randomized crossover study shows that consuming WP at *Suhoor* modestly but significantly reduced the number of fasting days interrupted due to hypoglycemia ($p = 0.008$),

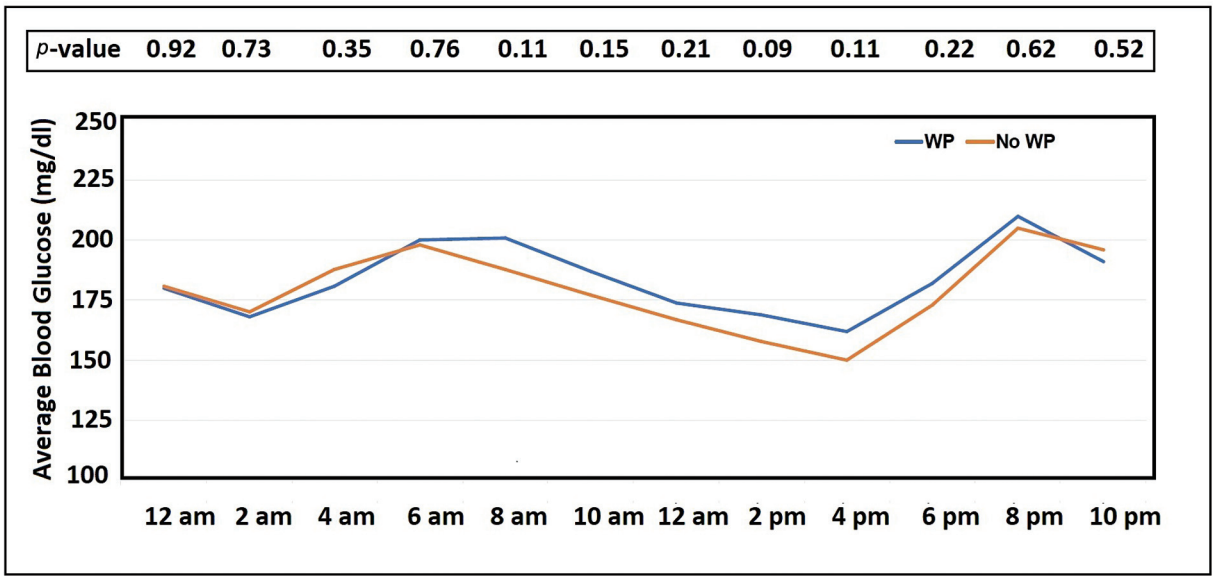

Fig. 3 Comparison of average hourly blood sugar during whey protein (WP) supplementation week versus non-WP supplementation week.

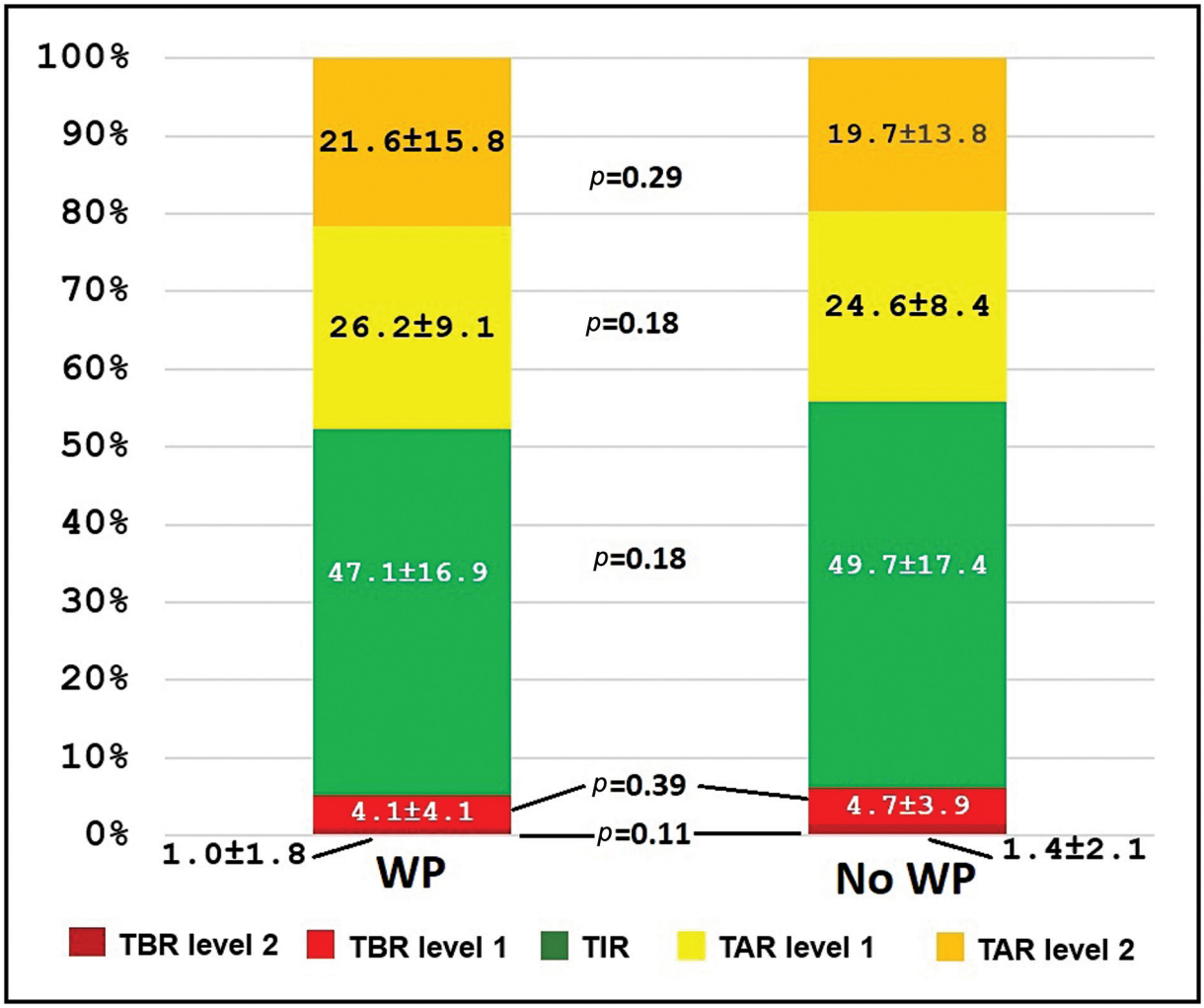

Fig. 4 Comparison of ambulatory glucose profile (AGP) report data during whey protein (WP) supplementation week versus no-WP supplementation. WP: Whey protein 24 mg in 200 mL low-fat milk. TBR, time below range; level-1: 70 mg/dL, level-2: 50 mg/dL; TIR, time in range, 70–140 mg/dL; TAR, time above range; level-1: 180 mg/dL, level-2: 250 mg/dL.

suggesting a real-world benefit for patients attempting prolonged fasting. The observed reduction in fast-breaking events is consistent with prior mechanistic data showing that WP can slow gastric emptying, increase satiety, and blunt postprandial glucose excursions, mediated in part by enhanced GLP-1 and insulin secretion.[6–9] These effects are time-dependent and more likely to impact glucose dynamics during the morning and early afternoon, which aligns with the timing of hypoglycemia observed in our cohort. Nevertheless, the morning hours (4–11 a.m.) were the most common period for hypoglycemia in both arms, consistent with patterns observed in previous Ramadan and fasting-related studies.[13,14] This is a physiologically vulnerable period following the predawn meal (Suhoor), when insulin remains active while nutrient availability declines. Although the distribution of hypoglycemia timing did not differ significantly between weeks ($p = 0.837$), the trend toward fewer early episodes in the WP week aligns with the proposed postprandial stabilizing effects of WP. It is also notable that CGM-detected hypoglycemic events were reduced near *Iftar* during the week of the WP, thereby reducing the risk of late-day complications.

In contrast to long-term studies in T2D,[9,10] where WP may increase fasting glucose or homeostasis model assessment for insulin resistance over time, our short-term fasting protocol showed no adverse glycemic effects, as reflected by stable CGM metrics, including average glucose, GMI, and glucose variability. Although CGM-detected hypoglycemia events by time of day showed only a nonsignificant trend toward fewer episodes with WP during the vulnerable periods of post-*Suhoor* and pre-*Iftar*, participants experienced significantly fewer fasting interruptions. This difference may reflect the fact that even small variations in hypoglycemia frequency can influence the decision to break a fast, while not being large enough to produce statistically significant changes in CGM-derived outcomes.

Evidence for the use of WP in T1D remains limited but is growing. Conn et al examined postprandial glycemic responses in youth with T1D on insulin pump therapy. They found that WP-only meals could be managed with reduced or omitted insulin boluses without triggering hypoglycemia, suggesting a glycemic-sparing effect of protein under certain circumstances.[11] Rath et al conducted a randomized crossover trial in adolescents with T1D showing that ingestion of 50 g WP 3 hours after exercise reduced overnight hypoglycemia, likely via stimulation of hepatic glucose output through glucagon and incretin pathways.[12] This is the first study to evaluate WP supplementation in T1D during Ramadan using a randomized controlled design and CGM-based outcomes. The use of WP at *Suhoor* appears to enhance fasting stability without significant risk of delayed hyperglycemia, unlike carbohydrate-heavy meals or aggressive basal insulin reductions. The intervention was well tolerated, and notably, 68.3% of participants expressed willingness to use WP again, underscoring its feasibility as a safe, practical, and culturally acceptable adjunct during Ramadan fasting.

Our study has several limitations. First, the modest sample size limited the power to detect smaller differences in secondary outcomes such as CGM-based glycemic metrics. However, the randomized crossover design strengthened the analysis by reducing interparticipant variability and effectively increasing the precision of comparisons. Second, while the crossover design reduces interparticipant variability, insulin adjustments were left to participant discretion. This reflects real-world Ramadan practice but may have introduced variability across intervention periods. Third, although the WP supplement and milk were standardized, the composition of the remainder of the Suhoor meal was not controlled and could have influenced the outcomes. Fourth, while CGM data were complete for all participants, fast-breaking behavior was self-reported and therefore subject to recall bias. Factors beyond CGM-detected hypoglycemia, such as subjective symptoms or capillary glucose readings, may have influenced it. Finally, this was a single-center study conducted in a relatively young Saudi cohort, which may limit generalizability to other Muslim populations with different dietary practices and cultural fasting traditions.

Conclusion

WP supplementation at *Suhoor* significantly reduced the number of fasting days interrupted due to hypoglycemia in individuals with T1D, without worsening glycemic control or increasing the risk of adverse events. These findings support WP as a safe and potentially beneficial dietary adjunct for patients with T1D who wish to fast during Ramadan. Larger trials are needed to confirm these effects and determine optimal dosing strategies. Moreover, although this study focused on objective glycemic outcomes, future research could explore the impact of nutritional strategies such as WP on perceived satiety, confidence in fasting, and quality of life.

In summary, WP supplementation at *Suhoor* is a promising strategy to reduce hypoglycemia-related fasting interruptions in individuals with T1D. Further large-scale, multicenter studies are warranted to confirm its role in clinical practice.

Study Registration at Clinicaltrials.gov
NCT06595550.

Authors' Contributions
All the named authors contributed to the conceptualization, planning, and conduct of the study. They all contributed to the drafting and revising of the manuscript and approved its final version.

Compliance with Ethical Principles
The study was approved by the institutional review board and conducted in accordance with the principles outlined in the Declaration of Helsinki (Ref IRB/0605/23).

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None.

Conflict of Interest
None declared.

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