Effect of Different Insulin Regimens on Individuals with Type 2 Diabetes during Ramadan Fasting in the DAR Global Surveys of 2020 and 2022

Mohamed Hassanein[1,2,3]   Khadija Hafidh[4]   Muhammad Yakoob Ahmedani[5]   Samih A. Odhaib[6]
Inass Shaltout[7]   Mohammed A. Batais[8]   Rulli Rosandi[9]   Mohamed Fariduddin[10]   Majid Alabbood[11]
Mehmet A. Buyukbese[12]   Tong C. Voon[13]   Rachid Malek[14]   Reem Al-Amoudi[15]   Abdulla Alzahrani[16]
Zanariah Hussein[17]

[1] Department of Diabetes and Endocrinology, Dubai Hospital, Dubai Academic Health Corporation, Dubai, United Arab Emirates
[2] Department of Medicine, Gulf Medical University, Ajman, United Arab Emirates
[3] Postgraduate Diabetes Education, Cardiff University, Cardiff, United Kingdom
[4] Diabetes Unit, Rashid Hospital, Dubai Academic Health Corporation, Mohamed Bin Rashid University (College of Medicine and Health Sciences), Dubai, United Arab Emirates
[5] Baqai Institute of Diabetology and Endocrinology, Karachi, Pakistan
[6] Faiha Specialized Diabetes, Endocrine, and Metabolism Center, University of Basrah, Basrah, Iraq
[7] Department of Medicine, Faculty of Medicine, Cairo University, Cairo, Egypt
[8] Diabetes and Chronic Disease Management, Department of Family and Community Medicine, College of Medicine, King Saud University, Riyadh, Saudi Arabia
[9] Internal Medicine Department, Fakultas Kedokteran Universitas Brawijaya, Dr. Saiful Anwar Hospital, Indonesia
[10] Department of Endocrinology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh

[11] Department of Medicine, Gold Coast University Hospital, Queensland, Australia
[12] Gaziantep Islam Science and Technology University, Gaziantep, Turkiye
[13] Department of Medicine, Malacca General Hospital, Malacca, Malaysia
[14] Service Médecine Interne, CHU Sétif, Algeria
[15] Endocrine Department, King Abdul-Aziz Medical City, King Saud Bin Abdulaziz University, Riyadh, Saudi Arabia
[16] Endocrine Department, King Saud bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia
[17] Department of Internal Medicine, Hospital Putrajaya, Putrajaya, Malaysia

Address for correspondence Khadija Hafidh, FRCP FACE, Diabetes Unit, Rashid Hospital, Dubai Academic Health Corporation, Mohamed Bin Rashid University (College of Medicine and Health Sciences), Dubai, United Arab Emirates (e-mail: khadija.hafidh@gmail.com).

Abstract

Introduction The DAR (Diabetes and Ramadan International Alliance) global surveys of 2020 and 2022 presented a unique opportunity to study the differences among various insulin treatment regimens during Ramadan fasting in individuals with diabetes to better understand the risks and complications associated with insulin therapy between the different regimens.

Patients and Methods Individuals with type 2 diabetes on an intensive insulin regimen were categorized into two cohorts: 1,527 receiving basal-bolus insulin (14.1%) and 1,355 on premixed insulin (12%). We examined the patterns of differences between the two cohorts concerning baseline characteristics, diabetes-related complications, dysglycemia occurrence, and hospitalization rates during fasting.

Results The mean age was similar between cohorts (56.0 ± 12.1 years in basal-bolus vs. 55.1 ± 11.3 years in premixed insulin). However, the basal-bolus group had a significantly longer diabetes duration (14.1 ± 8.4 vs. 12.5 ± 7.5 years, $p = 0.03$). Other metabolic

Keywords
► Ramadan fasting
► type 2 diabetes
► insulin regimen
► basal-bolus
► premixed insulin

parameters, including HbA1c, body mass index, blood pressure, and low-density lipoprotein cholesterol levels were not different. Insulin use was slightly higher in women in both groups. Proportions of those who fasted, practiced self-monitoring of blood glucose, and had access to Ramadan-focused education were similar in the two cohorts. The basal-bolus cohort had tended to have increased occurrence of hypoglycemic episodes (23.9% vs. 17.7%, $p = 0.08$) but similar rates of hypoglycemia (6.5%). Frequent hyperglycemia (≥ 8 days) and the hyperglycemia-related emergency visits and hospitalizations were significantly higher in the basal-bolus group (9.0% vs. 3.7%, $p < 0.001$).

Conclusion   Multiple-dose premixed insulin regimens in this study appear less prone to hyperglycemic episodes and hospitalizations. However, a causal relationship cannot be inferred as differences and variations in medical management, prescribing habits, and fasting practices across wider regions must be considered confounding factors. Carefully designed randomized-controlled studies are needed to establish a definitive link.

Introduction

Many individuals with type 2 diabetes (T2D) on insulin therapy fast irrespective of their risk level and their physicians' advice. Physicians are required to assess the individual's intention to fast and provide guidance for a safe fasting experience.[1] The IDF-DAR (International Diabetes Federation and Diabetes and Ramadan International Alliance) Practical Guidelines 2021 recommend the application of a risk calculator that considers 14 different risk elements, each with a separate scoring system. The cumulative score indicates the individualized risk category for fasting.[2]

With regards to glucose-lowering therapies, individuals treated with multiple-dose insulin therapy, either with premixed insulin or basal-bolus insulin regimen, are identified to have the highest risk scores for this specific risk element, highlighting the need for special precautions and careful consideration for this particular cohort of patients who are potentially at risk of glycemic-related complications during Ramadan fasting (RF).[3]

Although insulin use during fasting increases the risk of hypoglycemia, especially with complex regimens, glycemic control during Ramadan also requires careful management and should not be compromised.[4]

Maintaining blood sugar control reduces the risk of T2D complications, especially vascular issues. However, complex insulin regimens can hinder adherence due to fear of hypoglycemia and dosing challenges.[5] Intensive insulin therapy with multiple daily injections lowers HbA1c and improves long-term outcomes, however, increases the risk of severe hypoglycemia.[6]

Few studies have evaluated insulin regimens during Ramadan; large randomized controlled trials (RCTs) are still lacking.[2] The DAR global surveys of 2020 and 2022 gathered demographic, clinical, and fasting data from 10,788 individuals with T2D. It serves as a platform to analyze insulin regimens across different regions.[6,7] The objective of the sub-analysis is to compare the effects of basal-bolus and premixed insulin regimens on glycemic control, hypoglycemia, and hyperglycemia incidence during RF among individuals with T2D surveyed in 2020 and 2022.

Patients and Methods

Design and Settings

A cross-sectional survey (2020 and 2022) evaluated Muslim individuals with T2D on insulin who chose to fast during Ramadan. Many Muslim majority countries, including Bahrain, Bangladesh, Brunei, Egypt, Indonesia, Iraq, Iran, Jordan, Libya, Saudi Arabia, Malaysia, Singapore, Pakistan, Türkiye, the United Kingdom, and the United Arab Emirates, participated in the survey. For methodological consistency, the same survey questions were used across 2020 and 2022.

Study Population

Muslim individuals with diabetes were invited to participate in the study during clinic consultations within the 10-week post-Ramadan period. To ensure a diverse representation of diabetes care across different countries, the study included health care professionals from various specialties, including endocrinologists, general practitioners, and internal medicine physicians.

Data Synthesis

Muslim individuals who regularly attended outpatient diabetes care, provided informed consent, had a confirmed diagnosis of T2D, and were on either a premixed insulin or basal-bolus regimen met the inclusion criteria. Individuals with type 1 diabetes, pregnancy, and those who did not fast were excluded from this subgroup analysis. A subset of patients classified as "high risk"—those who required emergency room visits or hospitalization due to hypo- or hyperglycemia or experienced frequent hypoglycemia (more than eight episodes per Ramadan)—underwent additional analysis. Compliance with medications, pre-Ramadan hypoglycemia data, dietary intake pattern, physical activity, and sleep habits were not evaluated.

Statistical Analysis

Descriptive statistics were used to describe the clinical aspects and the baseline demographics. A continuous variable's mean and standard deviation were used to describe it.

In contrast, each event's frequency (%) and percentage were used to characterize categorical variables based on the provided information. The total number of values changes depending on the data provided for each measurement. A combined description was given for the 2020 and 2022 DAR global survey data, and the study did not consider missing values. The primary outcomes data were categorized solely on treatment regimen, with those on a basal/bolus treatment plan pitted against those on mixed insulin therapy. Pearson's chi-square test was employed to investigate the disparity between the two groups. A p-value of less than 0.05 was considered statistically significant for the two-sided statistical tests. The data were analyzed using IBM SPSS Statistics version 26 (Armonk, New York, United States).

Results

Characteristics of Patients
A total of 10,788 individuals with T2D participated in the surveys, of whom 1,527 (14.1%) were on a basal-bolus regimen and 1,355 (12.6%) on premixed insulin therapy (►Table 1). ►Fig. 1 illustrates the geographical distribution of the individuals with T2D on both insulin regimens in this study.

Correlates of Insulin Use and Doses
The mean age was not significantly different between cohorts (56.0 ± 12.1 vs. 55.1 ± 11.3 years, NS) in the basal-bolus and premixed insulin cohorts, respectively. Insulin use was marginally more among women in both groups (55.5% in basal-bolus vs. 53% in premixed insulin). However, the basal-bolus group had a significantly longer diabetes duration (14.1 ± 8.4 vs. 12.5 ± 7.5 years, $p = 0.03$). Other metabolic parameters, including HbA1c, body mass index (BMI), blood pressure, and low-density lipoprotein levels, showed no significant differences (►Table 1).

Complications, Monitoring, and Education
Diabetes-related complications and comorbidities were significantly higher in the basal-bolus cohort, as shown in ►Fig. 2. ►Table 2 depicts the fasting patterns, self-monitoring of blood glucose (SMBG), and Ramadan-specific diabetes education in the basal-bolus and premixed insulin cohorts. Although no statistical significance was found with all segments of fasting duration falling at $p > 0.05$, more patients in the premixed insulin group fasted during Ramadan (88.5% vs. 80.1%, $p = 0.5$). The post-RF (Shawal) rates were similar (23% vs. 24.3%, $p = 0.7$) with no statistical significance. The SMBG and Ramadan-specific diabetes education were comparable between the groups, with no significant difference ($p = 0.9$).

Frequency of Complications
►Fig. 3 illustrates the incidence of diabetes-related complications in individuals with T2D who fasted for different durations in Ramadan while on insulin therapy in both cohorts. Hypoglycemia was more frequent in the basal-bolus cohort (23.9% vs. 17.7%) for the premixed insulin group. The emergency department visits or hospitalizations for hypoglycemia occurred at a similar rate (6.5% in both groups).

Hospitalizations
However, hyperglycemia-related emergency visits and hospitalizations were significantly higher in the basal-bolus group (9.0% vs. 3.7%, $p < 0.001$), given the fact that they encountered more frequent hypo- and hyperglycemia episodes (≥ 8 per Ramadan) when using the basal-bolus insulin

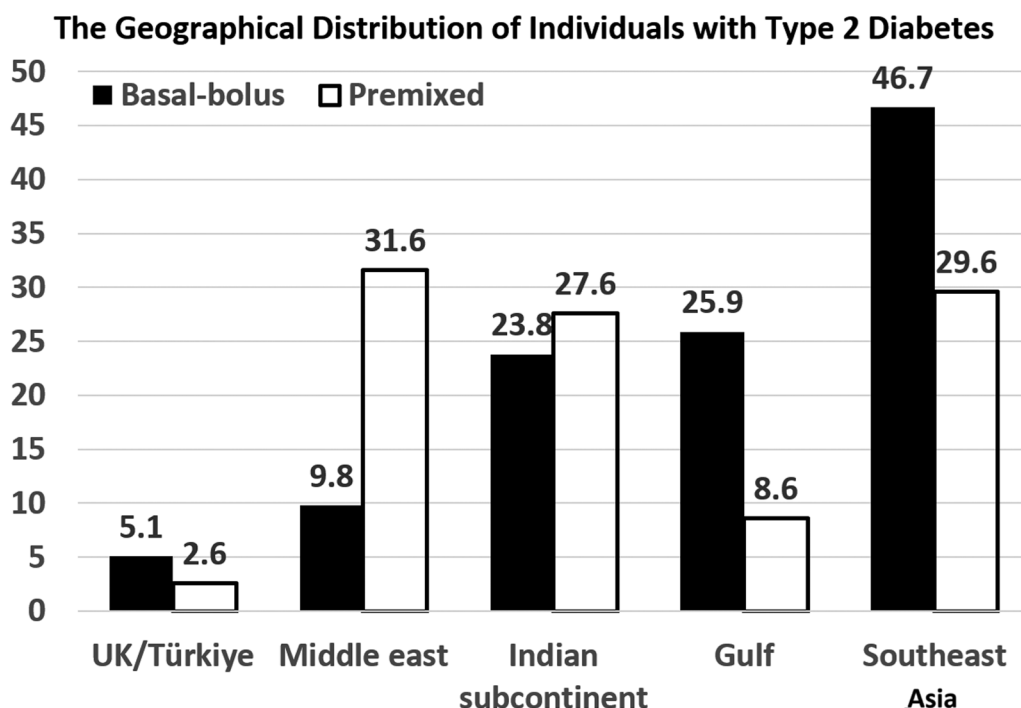**The Geographical Distribution of Individuals with Type 2 Diabetes**

Fig. 1 The geographical distribution of individuals with T2D. T2D, type 2 diabetes.

Prevalence of Diabetes-Related Complications and Comorbidities in Basal-Bolus and Premixed Insulin Cohorts
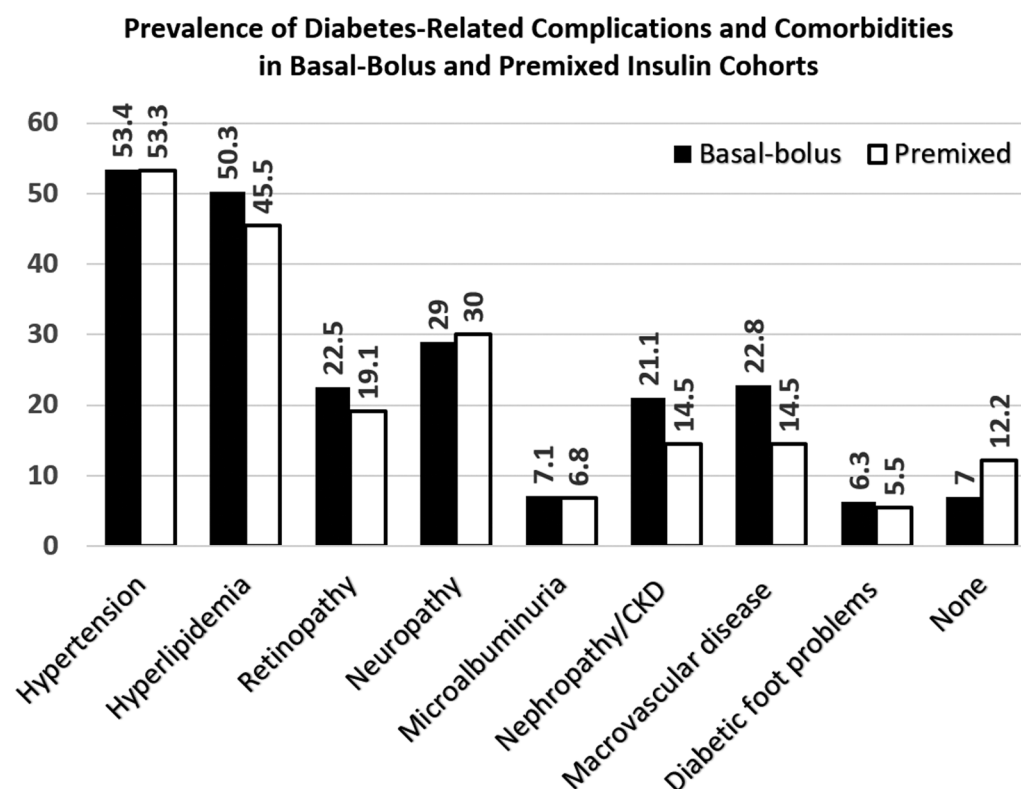

Fig. 2 Prevalence of diabetes-related complications and comorbidities in basal-bolus and premixed insulin cohorts.

regimen. Among patients requiring hospitalization or frequent emergency visits, those in the basal-bolus group had significantly higher rates of retinopathy, microalbuminuria, nephropathy, and hyperlipidemia compared with the premixed insulin cohort (►**Fig. 4**).

Discussion

Due to the progressive nature of pancreatic β cell loss during T2D, many patients will eventually require insulin therapy.[8] In insulin-naive individuals with T2D, insulin therapy is usually initiated with simple, single-daily injection regimens, such as once-daily basal or premixed insulin. With a longer duration of diabetes and failure of optimal glycemic control while on a combination of oral glucose-lowering therapies and single-dose insulin regimens, intensification to multiple-dose insulin regimens, such as a basal-bolus insulin regimen or two or three doses of premixed insulin, is then necessary.

Insulin therapy has several established negative associations, such as increased risk of hypoglycemia (particularly during Ramadan and with the use of human insulin), non-adherence to injections, inappropriate timing of insulin injections, incorrect insulin injection techniques, suboptimal insulin dose adjustment and titration, inadequate self-blood glucose monitoring, and being a sign of a worsening disease condition, among other reasons.[9]

RF entails a significant shift in lifestyle practices and behaviors beyond simply abstaining from food. Addressing these lifestyle modifications is crucial and challenging for individuals with T2D. The DAR global survey, a post-Ramadan population-based study conducted across more than 20

countries (the majority of which had predominantly Muslim populations) in 2020 and 2022, found that 85.4% of individuals with T2D observed RF. Among those on insulin therapy, 79% chose to observe the fast.

While insulin therapy can typically be titrated to achieve regulated fasting plasma glucose levels, many patients will eventually require more intensive insulin replacement by adding prandial insulin to basal insulin.[10]

Limited data are available regarding the optimal insulin type or regimen for patients with T2D during Ramadan.[5] The current body of evidence does not support one insulin treatment regimen over another; however, this analysis of the DAR global survey provides real-world data on a large number of individuals with T2D (over 2,800) who received intensive insulin therapy during Ramadan. More frequent cardiovascular complications occurred with basal-bolus insulin treatment (►**Table 2**). Surprisingly, more complication-free patients were in the premixed insulin cohort (12.2% vs. 7%). More patients fasted during Ramadan in the premixed insulin cohort (88.5% vs. 80%). Among them, significantly more patients completed the entire month of fasting (59.1% vs. 50%) in the premixed insulin and basal-bolus insulin cohorts, respectively. This observation may be due to the premixed insulin regimen being more straightforward to adjust and modify to the particular nature of RF. Premixed insulins tend to be better suited for individuals with predictable meal patterns.[11]

The CREED study demonstrated hypoglycemia as the most common risk associated with insulin therapy, but did not elaborate on the effect of a specific type of insulin regimen on hypoglycemia incidence.[12] Our real-world data

Table 1 Baseline characteristics and metabolic parameters of individuals with T2D on basal-bolus and premixed insulin regimens

Parameters		Basal bolus insulin, $N = 1,527$	Premixed insulin, $N = 1,355$	p-Value
Age (y)	<40	9.5%	7.7%	0.3
	40–49	16.8%	23.2%	0.06
	50–59	30.9%	31%	0.98
	≥60	42.8%	38.1%	0.5
	Mean (SD)	56 ± 12.1	55.1 ± 11.3	0.9
Diabetes duration (y)	<10	30.9%	38.3%	0.4
	10–19	41.5%	41.6%	0.98
	≥20	27.6%	20.1%	0.06
	Mean (SD)	14.1 ± 8.36	12.5 ± 7.5	0.03
Sex	Female	55.5%	53%	0.5
	Male	44.5%	47%	
HbA1c (%)	<7.5	20.9%	24.1%	0.4
	7.5–9.0	33.4%	37.4%	0.5
	>9	45.7%	38.5%	0.3
	Mean (SD)	9.2 ± 2	8.85 ± 1.8	0.8
BMI (kg/m^2)	Mean (SD)	28.2 ± 7.3	27.2 ± 6.55	0.8
SBP (mmHg)	Mean (SD)	133.4 ± 24.4	131.6 ± 25.6	0.9
DBP (mmHg)	Mean (SD)	76.8 ± 14.2	76.6 ± 15	0.9
LDL-C (mg/dL)	Mean (SD)	113.5 ± 49.9	106 ± 45.2	0.6
Medication 1: non-insulin	Metformin	56.6%	69.1%	0.03
	DPP4 inhibitors	23.4%	28%	0.3
	Thiazolidinedione	1.8%	11%	<0.0001
	SGLT2i	17.2%	21.4%	0.2
	GLP1-RA	5.2%	1.2%	<0.0001
	AGI	0.5%	1%	0.17
Medication 2: insulins	Intermediate-acting	39%	0	–
	Long-acting	61%	0	–
	Short-acting	100%	0	–
	Combination	0	100%	–

Abbreviations: AGI, alpha-glucosidase inhibitor; BMI body mass index; DBP, diastolic blood pressure; DPPIV, dipeptidyl peptidase 4 inhibitors; GLP1 RA, glucagon like peptide receptor agonists; HbA1c, glycated hemoglobin; LDL-C, low-density lipoprotein cholesterol; SBP systolic blood pressure; SD, standard deviation; SGLT2i, sodium-glucose transporter 2 inhibitor.

suggest that both hypo- and hyperglycemia were of significantly higher incidence in the basal-bolus insulin regimen versus the premixed insulin regimen (►**Fig. 3**), a result at odds with a previous study that found no significant differences for glycemic control, hypoglycemia rate, or BMI between the basal-bolus and premixed insulin groups.[13] This discrepancy can be attributed to the considerable regional variations in the use of each regimen (►**Fig. 1**). A previous study found that insulin regimens differ substantially between European countries, reflecting variations in regulations, reimbursement systems, national diabetes care systems, and patient characteristics and expectations.[13,14]

During Ramadan, it is customary to experience dysregulation of regular eating patterns, with higher caloric and carbohydrate consumption in the evening meal that breaks the fast. This would explain the high rate of hyperglycemia experienced by both cohorts (32 and 23.7%). Still, the significantly higher rate of hospitalization in the basal-bolus cohort, at 9% versus 3.7% in the premixed insulin cohort ($p = 0.0002$), may be attributed to several baseline characteristics, such as older age, longer diabetes duration, and a higher proportion with poor glycemic control in that cohort, as demonstrated in ►**Fig. 4**.

Following a pre-Ramadan medical assessment and application of the RF risk calculator, individuals with T2D on an intensive insulin regimen would be assessed to have a higher

Table 2 Fasting patterns, self-monitoring of blood glucose (SMBG), and Ramadan-specific diabetes education in basal-bolus and premixed insulin cohorts

Parameters		Basal bolus insulin, $N = 1,527$	Premixed insulin, $N = 1,355$	p-Value
Fasted the month of Ramadan	Yes	80.1%	88.5%	0.5
Duration of Ramadan fasting (days)	1–7	3.5%	2.8%	0.4
	22–29	34.7%	28.6%	0.2
	30	50%	59.1%	0.3
	Mean ± SD	26.6 ± 6.3	27.2 ± 5.8	0.7
Intention for Shawal (post) Ramadan fasting	Yes	23%	24.3%	0.7
Did you do SMBG during Ramadan?	Yes, more frequent than before Ramadan	13.8%	12.4%	0.6
	Yes, less frequent than before Ramadan	14%	15.7%	0.5
	Yes, at the same frequency as before Ramadan	53%	47.5%	0.5
	No	19.2%	24.2%	0.2
Received education	Yes	58%	57.4%	0.9
Method of education	In the clinic, during my routine consultation	74.9%	72.6%	0.8
Duration of sessions	0–15 min	79.5%	75.8%	0.7

Abbreviation: SD, standard deviation; SMBG, self-monitoring of blood glucose.
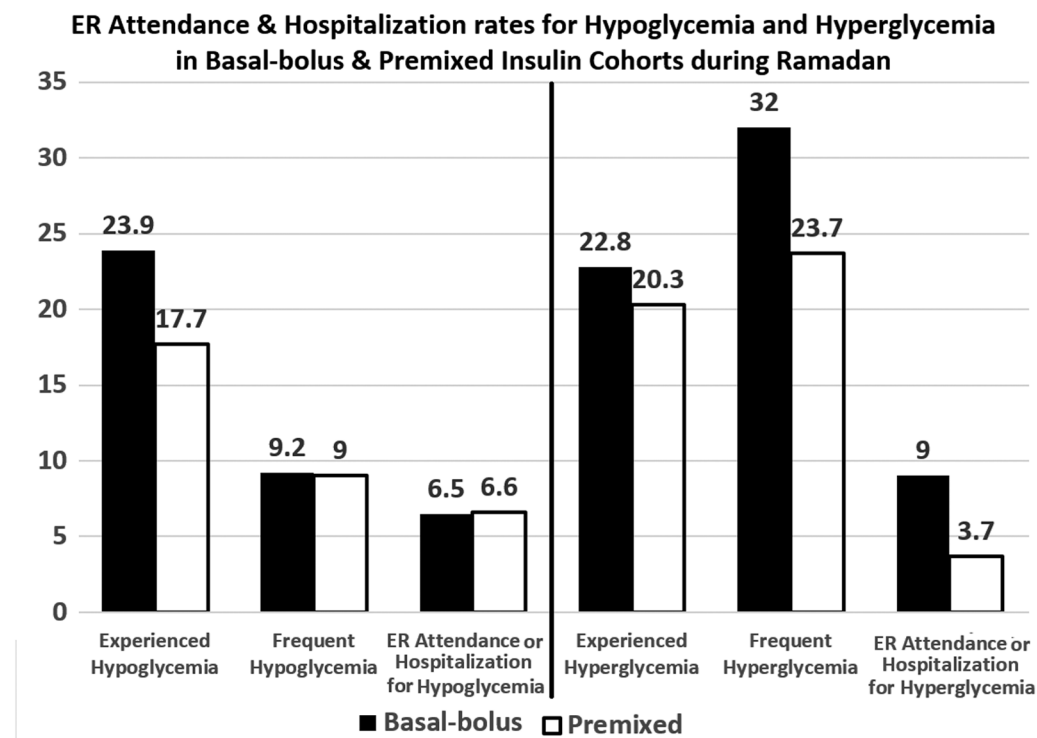
Fig. 3 Frequency of emergency room (ER) attendance and hospitalization for hypoglycemia and hyperglycemia in basal-bolus and mixed insulin cohorts during Ramadan.

risk score compared with other treatment options and are expected to receive Ramadan-focused patient education and to be advised to practice frequent SMBG. However, our data suggest otherwise. Only a minority of patients (13.8% in basal-bolus insulin and 12.4% in mixed insulin) performed SMBG more frequently than before Ramadan, and over two-fifths of them (some 42%) did not receive any specific patient education (►**Table 2**). This serves only to emphasize the

Potential Contributors to Hyperglycemia & Hospitalizations in Insulin-treated Individuals with Type 2 Diabetes during Ramadan
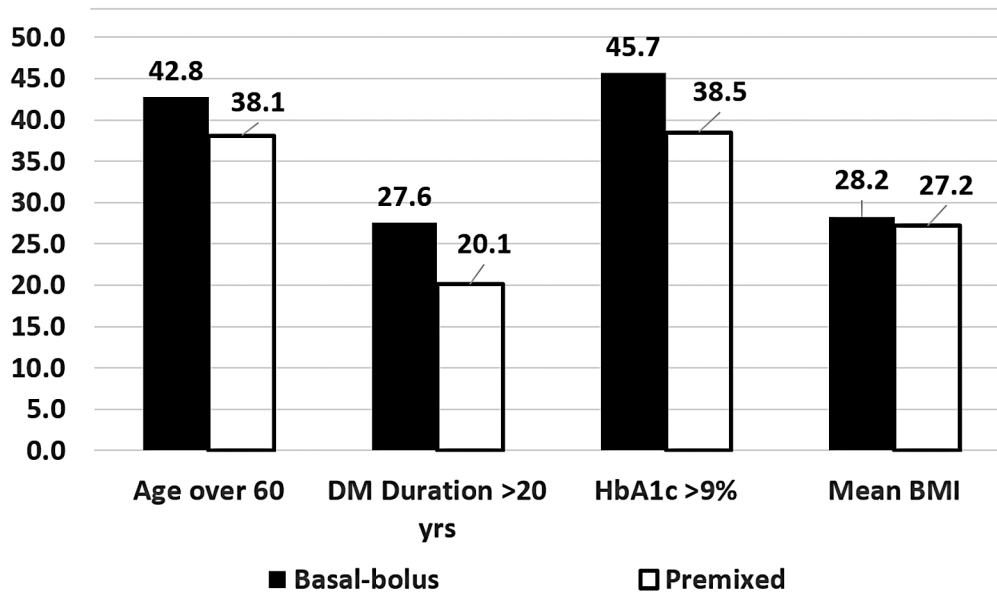

Fig. 4 Potential contributors to hyperglycemia and hospitalizations in insulin-treated individuals with T2D during Ramadan. T2D, type 2 diabetes. DM, diabete mellitus; HbA1c: glycosylated hemoglobin; BMI: body mass index.

importance of a strong push toward providing comprehensive, Ramadan-focused, structured diabetes education to this group of insulin-treated individuals with T2D.[15] Lack of Ramadan-specific education and infrequent blood glucose monitoring significantly increase the risk of both hypoglycemia and hyperglycemia in people with diabetes who fast. Without proper guidance, patients may mismanage medications, make poor dietary choices, and fail to recognize when to break the fast. Infrequent self-monitoring delays the detection of glucose abnormalities, raising the risk of complications like diabetic ketoacidosis or hospitalization.[2] Structured education and regular monitoring are essential to ensure safe fasting and reduce adverse outcomes.

Worse outcomes in patients on basal-bolus insulin during Ramadan are more likely due to underlying disease severity rather than the insulin regimen itself. These patients are usually on intensive insulin therapy because they have more advanced diabetes, with longer disease duration, multiple comorbidities, or poor baseline glycemic control. While basal-bolus regimens carry a higher risk of hypoglycemia if not adjusted properly during fasting, with adequate education and dose modification, they can be managed safely. Therefore, the poor outcomes seen in this group likely reflect the complexity of their condition, not just the type of insulin regimen.

This study has notable limitations. Since it was survey-based, it is not possible to infer a causal relationship from the data. Moreover, hypo- and hyperglycemia were not clinically verified and are subject to recall bias after the Ramadan period. Hypoglycemia and hyperglycemia were self-reported without validation using continuous glucose monitoring. Additionally, residual confounders—such as regional pre-

scribing norms and varying levels of patient education, as well as baseline disparities in diabetes severity and duration—may have influenced the outcomes. Post-Ramadan HbA1c and BMI data were also unavailable. Nevertheless, the large, multinational dataset offers valuable real-world insights.

Conclusion

This study presents the first large-scale, real-world analysis of T2D patients who fast during Ramadan, examining the impact of insulin regimens on diabetes-related risks. Findings suggest that premixed insulin may be more suitable for reducing hyperglycemia and hospitalizations during RF; however, RCTs are needed for confirmation. Prioritizing Ramadan-focused education, including glycemic control, insulin self-titration, hypoglycemia prevention, and frequent SMBG, is essential for safe fasting and improved outcomes in insulin-treated T2D patients.

Author Contribution
All named authors contributed to the conduct of the study, data collection and analysis, and drafting and finalization of the manuscript.

Compliance with Ethical Principles
The original surveys received ethics approval from all study sites, and consent was obtained from all participants. Permission to access data from both surveys is granted to all authors.

Data Availability Statement
Data are available upon reasonable request to the corresponding author.

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