



Outcomes of People with Type 2 Diabetes using Sulfonylureas versus Other Non-Insulin Antidiabetic Agents during Ramadan: The Diabetes and Ramadan (DaR) Global Surveys

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J Diabetes Endocrine Practice 2026;9:137–145.

Abstract

Background There is an increasing need to investigate fasting outcomes for Muslims with type 2 diabetes (T2D) who choose to fast during Ramadan. Although sulfonylureas (SUs) are widely used in T2D, concerns persist regarding their risk of hypoglycemia during prolonged fasting. Modern second-generation agents, particularly Gliclazide modified release (MR), have demonstrated improved pharmacokinetic stability and a lower risk of hypoglycemia compared with older sulfonylureas, such as glibenclamide. This study seeks to understand the reported fasting outcomes of patients using second-generation sulfonylureas during Ramadan.

Patients and Methods The Diabetes and Ramadan (DaR) global survey was conducted in 14 countries and investigated patients with T2D who fasted during Ramadan in 2020 and 2022. The survey was administered by health care practitioners after Ramadan and compared those who used second-generation sulfonylureas with those deemed to be in the low-risk group (LRG).

Results After excluding individuals with cardiovascular, renal, or foot complications, as well as those treated with insulin, 5,294 individuals were included in the analysis (mean age $\approx$ 53 years). Participants on sulfonylureas and those in the LRG showed

Keywords

- ▶ type 2 diabetes
- ▶ Ramadan
- ▶ fasting
- ▶ Gliclazide MR
- ▶ sulfonylureas
- ▶ hypoglycemia
- ▶ SMBG

similar fasting adherence, with over 90% completing the Ramadan fast. Among sulfonylurea users, Gliclazide MR had the highest proportion of fasting for the full month (77%) and the lowest reported incidence of hypoglycemia (10.3%), comparable to the LRG (7.9%, $p = 0.2$).

Conclusions Fasting outcomes among participants using second-generation sulfonylureas were comparable to those on lower-risk oral agents during the Ramadan fasting period. Gliclazide MR demonstrated the most favorable profile, with the highest fasting blood glucose control rate and the lowest frequency of hypoglycemia among the sulfonylurea group. These findings support the safe use of modern sulfonylureas during Ramadan, provided it is under appropriate medical supervision. Further prospective and randomized studies are warranted to confirm the comparative safety and optimize treatment selection for individuals with T2D who fast.

Introduction

Ramadan fasting (RF) holds deep cultural and religious significance for millions worldwide. The concurrent rise in global Muslim populations¹ and diabetes prevalence^{2,3} highlights a growing challenge: An increasing number of Muslims observing Ramadan while managing diabetes.⁴ Despite fasting being exempt for Muslims with serious health issues, many with diabetes, and in particular type 2 diabetes (T2D), will choose to fast.^{5–7} However, individuals with diabetes face unique challenges as they navigate the delicate balance between adhering to religious observance and managing their health.

The practice of fasting during Ramadan represents a significant shift in typical eating, sleeping, and wakefulness patterns. Likewise, fasting can have important implications for physiology. It can present a major challenge for those living with diabetes, of which the main concern is uncontrolled blood glucose levels, which can in turn lead to hypoglycemia and hyperglycemia,⁸ underscoring the need for tailored management strategies.^{9,10} Good management strategies include having an adequate risk-stratification plan with a health care provider before Ramadan and, if deemed appropriate, increasing self-monitoring of blood glucose (SMBG) and adhering properly to antidiabetic medications.¹¹ For people with T2D, non-insulin oral antidiabetic drugs (OADs) are usually prescribed prior to insulin.⁹ Sulfonylureas (SUs) are generally considered to have an increased risk of hypoglycemia, primarily due to their effect of increasing plasma insulin concentrations.^{12,13} However, the risk of hypoglycemia is not the same across all medications within the class of sulfonylureas, with many modern, second-generation drugs providing a more favorable risk profile.^{14–17} Numerous studies have demonstrated that second-generation sulfonylureas, such as Gliclazide, Gliclazide modified release (MR), and Glimepiride, are preferable to older drugs within the class, including glibenclamide.^{14,15} Gliclazide MR, in particular, offers a smooth 24-hour pharmacokinetic profile with hepatic metabolism and limited renal excretion, features that reduce hypoglycemia risk and make it poten-

tially safer during prolonged fasting. The risk for uncontrolled blood glucose levels is even higher during Ramadan. Many people with T2D who elect to fast during Ramadan will use sulfonylureas,¹⁸ and there is a clear lack of research that has directly investigated their use during Ramadan.¹⁹

Accordingly, there remains a need to better understand the safety and real-world outcomes of second-generation sulfonylureas during Ramadan, particularly in comparison with other non-insulin antidiabetic agents considered to have a lower risk. To this end, the DaR alliance has conducted a global survey to bridge this gap, focusing specifically on the fasting behaviors and experiences of adults with T2D who took sulfonylureas.

Patients and Methods

Study Design and Outcomes

This cross-sectional survey was conducted in 14 countries, many of which are Muslim-majority, to examine the characteristics of T2D patients who chose to fast during the holy month of Ramadan in 2020 and 2022. The following nations participated in the survey: Algeria, Brunei, Egypt, Indonesia, Iraq, Iran, the Kingdom of Saudi Arabia, Malaysia, Morocco, Pakistan, Singapore, Turkey, the United Kingdom, and the United Arab Emirates. Approval was sought and obtained from national and local research and ethics authorities within the relevant countries.

During the 10-week post-Ramadan period, Muslim patients with diabetes were invited to participate in the survey during their routine clinic appointments. Health care professionals representing general practitioners, internal medicine specialists, and endocrinologists were selected to participate in this study, reflecting the different levels of diabetes care in each country. The inclusion criteria were met by Muslim persons who frequented their diabetic clinic sessions, could give informed consent, and had a confirmed diagnosis of T2D.

The study participants included adults with T2D who used sulfonylurea (SU) and fasted during Ramadan. Adults with T2D who were on insulin-based therapies and those with any

of the following comorbidities were excluded: Macrovascular disease (coronary artery disease, heart failure, stroke or transient ischemic attack, peripheral vascular disease), diabetic foot complications, microalbuminuria, nephropathy, or chronic kidney disease (abnormal estimated glomerular filtration rate (eGFR) or serum creatinine). Participants were grouped by class of SU, for which survey variables were assessed. The comparator “low-risk group” (LRG) consisted of participants who met the same inclusion and exclusion criteria but did not use sulfonylureas. They were primarily treated with non-SU oral agents, such as metformin (alone or in combination with dipeptidyl peptidase-4 [DPP-4] inhibitors), and a smaller proportion used sodium glucose co-transporter 2 (SGLT2) inhibitors. The LRG had a similar mean glycated hemoglobin (HbA1c; 7.45%) and diabetes duration (6.1 years) to the sulfonylurea groups, as shown in ►Table 1.

Survey Details

Training was given to the investigators on how to conduct the study questionnaire. The attending physician conducted a questionnaire-based interview with the diabetic patient during regular clinic sessions. They also completed a questionnaire based on pertinent clinical notes, which inquired about demographic and baseline information (including age, gender, length of illness, diabetes complications, and course of treatment). Information was collected on RF intentions,

the total number of days fasted during Ramadan and Shawwal, symptoms and experiences of hypoglycemia and hyperglycemia during fasting, and attendance at an emergency care department at the hospital or admission to the hospital. The survey also inquired about the characteristics of diabetes education that were specifically focused on Ramadan and SMBG practices that took place during the holy month. There were no questions regarding food habits or physical activity in this survey. The survey was developed using a SurveyMonkey questionnaire. The 2020 DaR Global Survey study results were previously released; here, we report on the combined data from both 2020 and 2022 for statistical analysis.

Statistical Analysis

Descriptive statistics were used to describe both the clinical aspects and the baseline demographics. A continuous variable's mean and standard deviation (SD) were used to describe it. In contrast, the frequency (N) and percentage for each event were used to characterize categorical variables based on the provided information. A combined description was given for the 2020 and 2022 DaR Global Survey data. Pearson's chi-square test was employed to investigate the disparity between the two groups. When there were differences, additional comparisons were made using the chi-square test, and multiple testing was considered using the Bonferroni technique. All analyses were exploratory and

Table 1 Baseline characteristics of study participants

Characteristics		Gliclazide N = 484	Gliclazide MR N = 1,222	Glimepiride N = 830	Low-risk group N = 2,758
Gender (%)	Female	53.1	50.9	54.9	50.4
	Male	46.9	49.1	45.1	49.6
Age (years)	Mean; SD	55.0; 11.6	53.2; 11.1	52.7; 10.3	51.4; 11.9
	<40	10.8	11.7	10.5	15.3
	40–49	19.9	21.4	26.8	28.7
	50–59	30.3	35.2	33.7	30.4
	60+	39.0	31.7	29.0	25.6
Duration of diabetes (years)	Mean; SD	8.37; 7.0	8.27; 5.9	7.38; 5.6	6.14; 5.2
	<10	63.4	65.4	70.1	79.2
	10–19	28.2	27.8	26.6	18.1
	≥20	8.4	6.8	3.3	2.7
HbA1c (%)	Mean; SD	8.00; 3.8	7.96; 2.1	8.54; 5.3	7.45; 1.5
	<7.5	39.6	37.9	34.3	60.8
	7.5–9.0	40.6	36	42.5	27.1
	>9	19.8	20.7	23.2	12.1
Diabetes complications (%)	Hypertension	46.5	46.7	40.2	23.2
	Hyperlipidemia	43.4	42.3	31.4	23.1
	Retinopathy	6.4	6.7	2.2	2.2
	Neuropathy	11.2	13.4	25.3	6.2
	None	14.9	26	18.4	17.8

Abbreviations: HbA1c, glycated hemoglobin; MR, modified release.

Table 2 Fasting practices of participants with type 2 diabetes during Ramadan

		Gliclazide N = 484	Gliclazide MR N = 1,222	Glimepiride N = 830	Low-risk group N = 2,758
Fasted the month of Ramadan (%)	Yes	90.5	93.6	90.6	92.4
	No	9.5	6.4	9.4	7.6
Duration of fasting (days)	Mean; SD	27.77; 5.12	28.39; 4.6	27.49; 5.4	27.74; 5.7
	1–7	1.8	1.7	1.7	0.1
	8–14	1.2	2	3.6	1.2
	15–21	7.1	2.7	5.9	4.4
	22–29	25.1	16.2	29.2	21.8
	30	64.8	77.4	59.6	72.5
Duration of break of Ramadan fasting (days)	Mean; SD	1.84; 5.33	0.87; 3.88	1.19; 4.00	1.41; 4.58
	1–7	92.6	97.3	94.9	96.6
	8–14	4.8	1.0	3.0	2.1
	15–21	0	0.4	1.1	1.1
	22–29	2.6	1.3	1.0	0.1
Intention for Shawal (post) Ramadan fasting (%)	Yes	28.7	32.3	21.3	27.3
	No	71.3	67.7	79.7	72.7

Abbreviation: MR, modified release.

intended to identify associations rather than causal effects, given the cross-sectional design. For each of the two-sided statistical tests that were employed, a *p*-value of less than 0.05 was considered statistically significant. The data were analyzed using IBM SPSS Statistics version 26.²⁰

Results

A total of 6,522 participants with T2D were asked to participate in a survey during and after Ramadan 2020 and 2022. Of these, 607 were using Gliclazide, 1,517 were using Gliclazide MR, 988 were using Glimepiride, and 3,410 were deemed in the LRG. Approximately 81% of participants completed the survey questionnaire (►Table 1). The highest proportion of participants came from the Gulf countries, the Middle East, the Indian subcontinent, and Southeast Asia. The mean age ranged from 51 to 55 years across groups, and there was a slightly higher proportion of female participants. The mean duration of diabetes ranged from 6 to 8.4 years, and HbA1c varied from 7.45 to 8.54. The most used concomitant medications were metformin and DPP-4 inhibitors, and the commonest complications were hypertension and hyperlipidemia. There were no meaningful differences in the measurements for body mass index (BMI), blood pressure (BP), or low density lipoprotein cholesterol (LDL) levels.

Fasting Intentions and Outcomes during Ramadan

There were no substantial between-group differences in the proportions of participants who fasted during Ramadan, and the average proportion across Gliclazide, Gliclazide MR, and Glimepiride users was 91.6%, compared with 92.4% in the LRG. More participants completed the entire month of fasting than those who did not across all groups.

Gliclazide MR users had the highest proportion who fasted the full month (77.4%) and took the fewest days off fasting (mean, 0.87 days), whereas Gliclazide users took the longest breaks (1.84 days; ►Table 2). The intention to fast during Shawwal was highest among participants using Gliclazide MR and Gliclazide compared with Glimepiride and the LRG.

Hypoglycemia during Ramadan

Among the sulfonylureas, the proportion of participants who experienced hypoglycemia during Ramadan was lowest in those using Gliclazide MR. Compared with participants using gliclazide, those using Gliclazide MR had significantly fewer episodes of hypoglycemia (-5.4% , $p < 0.001$). There was little evidence of a difference in the proportion of reported hypoglycemia episodes between the groups of Gliclazide and Glimepiride, and between Gliclazide MR and Glimepiride ($+3\%$, $p = 0.075$; -2.4% , $p = 0.11$, respectively). Compared with LRG, both gliclazide ($+7.8\%$, $p < 0.001$) and glimepiride ($+4.8\%$, $p = 0.018$) users had higher hypoglycemia rates, while Gliclazide MR showed a numerically higher but statistically non-significant difference ($+2.4\%$, $p = 0.2$; ►Fig. 1A).

The data showed a slightly higher proportion of participants reporting a duration of hypoglycemia of more than 8 days in those taking gliclazide compared with the LRG. Notably, the proportion of those taking Glimepiride was more than double the LRG for hypoglycemia lasting longer than a week. In this survey, “8 days” referred to the cumulative number of fasting days during which hypoglycemia symptoms were experienced, not a single prolonged episode (►Fig. 1B). As with the rates of cases of hypoglycemia, those taking Gliclazide MR were similar in duration of hypoglycemia compared with the LRG. Gliclazide MR users also showed

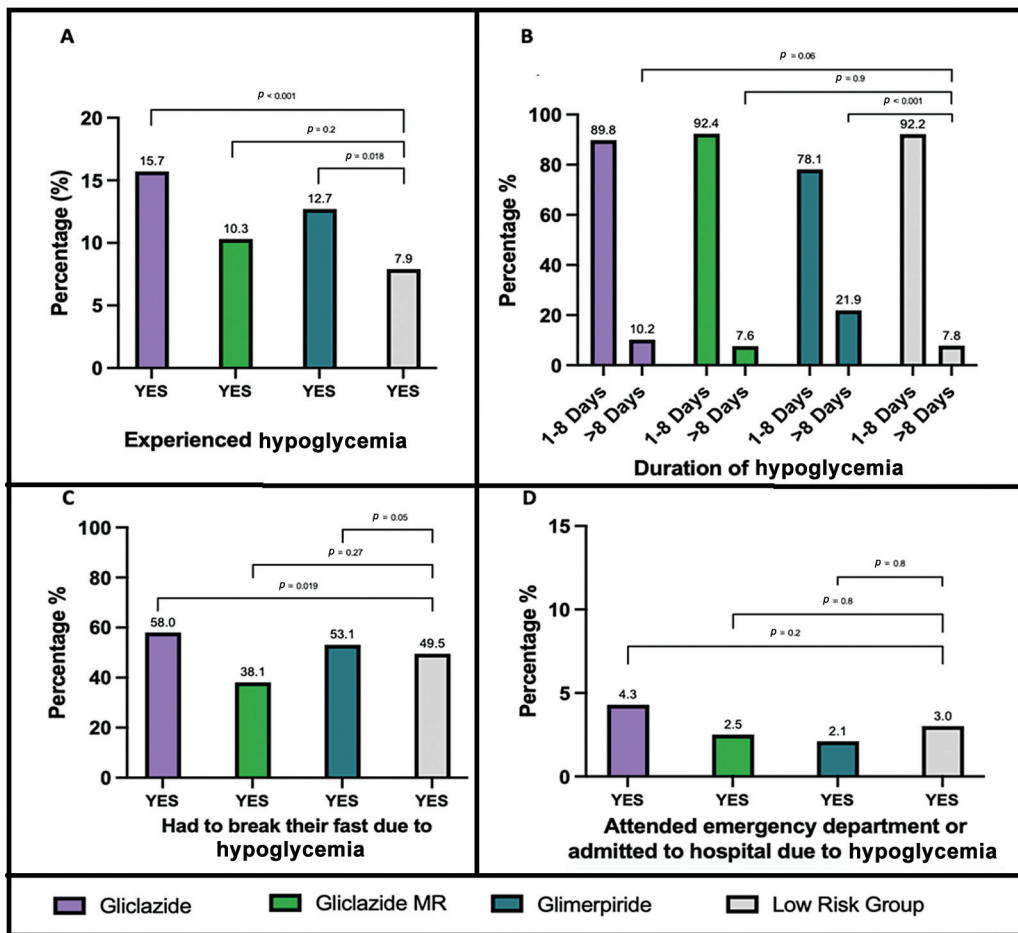


Fig. 1 Hypoglycemia during Ramadan fasting by treatment group. (A) Proportion of participants reporting hypoglycemia. (B) Duration of hypoglycemia episodes. (C) Participants who broke their fast due to hypoglycemia. (D) Participants requiring an emergency department visit or hospitalization for hypoglycemia. MR, modified release.

significantly shorter cumulative durations than Glimepiride users ($p < 0.001$).

The proportion of participants reporting that they needed to break their fast due to hypoglycemia during Ramadan was similar between those using Gliclazide MR and the LRG (-11.4% , $p = 0.27$). However, this measure was higher among those taking either Gliclazide or Glimepiride compared with the LRG. Hospitalization or emergency department attendance due to hypoglycemia was infrequent and did not differ significantly between any sulfonylurea group and the LRG ($\rightarrow$ Fig. 1D).

Hyperglycemia during Ramadan

The proportion of participants reporting hyperglycemia during RF was similar across all groups. Each sulfonylurea class did not exhibit meaningful differences in reported hyperglycemia episodes compared with the LRG. The distribution of the reported duration of hyperglycemia episodes, however, differed across drug classes. Using the number of hyperglycemia cases among those who fasted as the denominator, both Gliclazide MR and Glimepiride showed higher proportions of episodes lasting >7 days compared with the LRG. In contrast, Gliclazide users had the lowest

proportion (8.8%), which was significantly lower than the LRG (-11.1% , $p < 0.001$; $\rightarrow$ Fig. 2B). This difference may reflect the smaller number of total hyperglycemia cases in the Gliclazide group.

Participants using any sulfonylurea class were less likely to interrupt fasting due to hyperglycemia compared with those in the LRG ($\rightarrow$ Fig. 2C). Rates of hospitalization or emergency visits were low across all groups, with no clinically significant between-group differences ($\rightarrow$ Fig. 2D).

Self-Monitoring of Blood Glucose during Ramadan Fasting

For all participant groups, the largest proportion reported conducting SMBG at the same frequency as before the Ramadan period. The highest proportion of participants who reported no SMBG at all during Ramadan was those in the Glimepiride group (34.2%), followed by Gliclazide (28.6%). Gliclazide (40.8%) and Gliclazide MR (45.1%) users were most likely to check glucose at least once daily, slightly exceeding the LRG (37.8%). The lowest daily SMBG rates were among those using Glimepiride (29.7%; $\rightarrow$ Table 3).

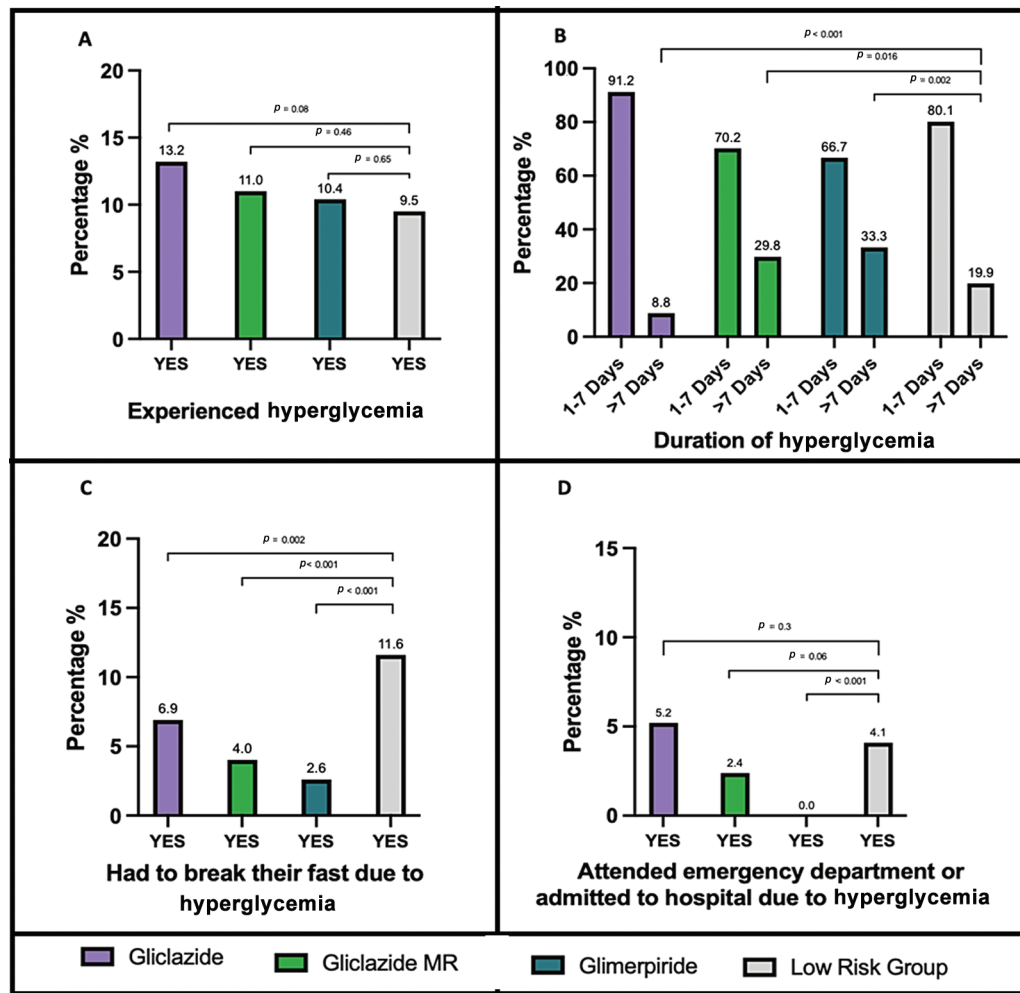


Fig. 2 Hyperglycemia during Ramadan fasting by treatment group. (A) Proportion of participants reporting hyperglycemia. (B) Duration of hyperglycemia episodes. (C) Participants who broke their fast due to hyperglycemia. (D) Participants requiring emergency department visit or hospitalization for hyperglycemia. MR, modified release.

Table 3 Self-monitoring blood glucose during Ramadan fasting^a

		Gliclazide N = 438 (%)	Gliclazide MR N = 1,144 (%)	Glimepiride N = 752 (%)	Low-risk group N = 2,548 (%)
Did you self-monitor blood glucose during Ramadan?	Yes, more frequent than before Ramadan	9.9	14.3	13.3	8.6
	Yes, less frequent than before Ramadan	16.3	15.1	13.1	12.6
	Yes, at same frequency as before Ramadan	41.8	70.5	39.6	49.1
	No	31.9	28.6	34.2	29.7
Frequency of self-monitoring blood glucose	Less than once weekly	27.0	19.6	36.3	28.2
	Once weekly	13.9	15.5	14.8	14.6
	2–4 times weekly	18.2	19.8	19.2	19.4
	Once daily	18.2	14.0	10.6	15.4
	Twice daily	18.0	23.3	16.6	17.2
	3–4 times daily	4.6	7.8	2.5	5.2

Abbreviation: MR, modified release.

^aDenotes who fasted during Ramadan.

Discussion

The findings of this survey highlight the reported behaviors and outcomes of individuals who fasted during Ramadan in 2020 and 2022. The results show little difference between participants who reportedly took sulfonylureas compared with those in the LRG for experienced outcomes during RF. Indeed, all groups had very high rates of fasting, which is not surprising considering that those with cardiovascular, renal, or foot complications, as well as insulin users, were excluded from the analysis. Among sulfonylurea users, Gliclazide MR was associated with the highest fasting completion rate and the lowest frequency of hypoglycemia episodes (►Fig. 1A–C), while overall fasting outcomes for sulfonylurea users were comparable to those in the LRG for hyperglycemia (►Fig. 2A–D).

This study has several strengths. The present global survey recruited participants from across several regions with large Muslim populations, providing an accurate account of the fasting patterns and behaviors from different geographical climates, cultural practices, and culinary preferences. Health care professionals administered this survey to patients, thereby increasing the validity of the collected data. Moreover, the relative sample size was large, allowing for precise estimates and a more representative sample of Muslim populations worldwide. There was a good balance across groups in many aspects of baseline characteristics, with small differences noted in HbA1c and duration of diabetes, as shown in ►Table 1. This study also assessed various aspects related to hypoglycemic or hyperglycemic episodes. The questionnaire assessed the severity, duration, need to stop the fast, and any hospital or emergency room admission related to such episodes.

This study also has its limitations. The scope of this survey is global, and not all regions with significant Muslim populations were studied, which limits the generalizability of the findings to the sampled regions. The nature of questioning patients post-RF may introduce recall bias or reduce the reliability of responses; however, this was mitigated by facilitation from health care professionals. The diagnosis of hypoglycemia and hyperglycemia was based on symptoms and may lead to an overestimation of these conditions; however, this was the same across all groups, so it should not invalidate any cross-group comparisons. Residual confounding due to variation in concomitant medications, glycemic control, and diabetes education may still exist, as treatment allocation was not randomized. Finally, as this was a cross-sectional analysis, associations should not be interpreted as causal, and future longitudinal or interventional studies are warranted.

In-line with previous studies showing the relative success of sulfonylurea use during RF,^{15,21} our results indicate that individuals using second-generation sulfonylureas, including Gliclazide, Gliclazide MR, and Glimepiride, can fast as well as those on lower-risk medications such as metformin. Importantly, sulfonylureas are still widely used among people living with T2D,^{22,23} and, therefore, Muslims seeking to fast during Ramadan. Indeed, this study finds that over 90% of

participants using sulfonylureas fasted during the month of Ramadan, which was marginally lower than the rate among people on safer medications in the designated lower-risk group (92.4%).

Sulfonylureas have generally been designated at a higher risk level during periods of fasting due to their associated increased risk of hypoglycemia. However, growing evidence—including this analysis—supports that modern second-generation sulfonylureas, particularly Gliclazide MR, exhibit a safer profile with minimal additional risk.^{16,24,25} Results from this study show that Gliclazide MR had similar rates of hypoglycemia episodes to those of people deemed lower risk, agreeing with what has been seen elsewhere.²¹ The Steadfast study also found that the DPP-4 inhibitor, Vildagliptin, was associated with fewer episodes of symptomatic hypoglycemia than gliclazide, which agrees with the results presented here, where Gliclazide and Glimepiride were found to be associated with higher symptomatic hypoglycemia events than the lower-risk participants. Within the current survey, Gliclazide MR consistently demonstrated a lower frequency and shorter duration of hypoglycemia than Glimepiride (►Fig. 1B) and fewer fasting interruptions (►Fig. 1C).

Al Sifri et al showed that the rates of hypoglycemia were lower among participants who used gliclazide compared with Glimepiride¹⁴; however, that study included both Gliclazide and Gliclazide MR, with no direct comparison between the two. Others have also reported differences in glucose control and the risk of hypoglycemia between second-generation sulfonylureas, with the GUIDE study finding that Gliclazide MR has a lower risk than Glimepiride.²⁶ These findings, together with ours, suggest a hierarchy within the second-generation class, in which Gliclazide MR may represent the safest sulfonylurea choice for patients intending to fast, but confirmatory prospective studies are required.^{19,26,27}

The reported rates of hyperglycemia among participants using sulfonylureas were not different from those in the lower-risk group. Among all groups, the mean HbA1c was moderately high, highlighting the need for better overall glycemic control among those with T2D. Interestingly, although the rates of hypoglycemia were higher in the Gliclazide group compared with the LRG group, the opposite was observed for hyperglycemia: Individuals in the Gliclazide group had significantly lower reported rates of episodes lasting more than a week (►Fig. 2B).

There is a need for individuals with T2D who are fasting and on sulfonylurea therapy to have more frequent SMBG, which is vital for improving outcomes during RF.^{11,28} This may explain why participants using Gliclazide and Gliclazide MR—both of which showed more favorable outcomes—also reported the highest daily SMBG frequency (►Table 3). Continuous patient education and reinforcement of SMBG remain key components of safe fasting.

Conclusion

This study reports the outcomes of individuals with T2D who used second-generation sulfonylureas during RF. The

findings demonstrate that second-generation sulfonylureas are broadly comparable to lower-risk non-sulfonylurea agents in terms of fasting intentions, duration of fasting, and rates of hypoglycemia and hyperglycemia. There may also be differences in outcomes among these second-generation sulfonylureas, with Gliclazide MR showing more favorable outcomes compared with Gliclazide and Glimepiride, which requires further investigation. Taken together, these results support the safe continuation of second-generation sulfonylureas, particularly Gliclazide MR, during Ramadan under structured medical guidance and patient education.

Authors' Contributions

All the named authors contributed toward conception, data collection, writing, and final approval of the manuscript.

Ethical Approval

Ethical approval for the DaR Survey was granted by the Dubai Health Authority.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of Interest

None declared.

Acknowledgments

The authors thank the assistance they received for medical writing provided by MYBIOME Ltd. This was unconditionally funded by Servier.

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