Glycemic Control and Satisfaction During Ramadan in Patients with Type 1 Diabetes Treated with an Advanced Hybrid Closed Loop Insulin Pump

Najoua Messaoudi¹, Nisrine Bouichrat¹, Imane Assarrar¹, Nabila Zeryouh¹, Siham Rouf^{1,2}, Hanane Latrech^{1,2}*

'Department of Endocrinology-Diabetology and Nutrition, Mohammed VI University Hospital Center, Faculty of Medicine and Pharmacy, University of Mohammed 1st, Oujda, Morocco. ²Laboratory of Epidemiology, Clinical Research and Public Health, Faculty of Medicine and Pharmacy, University of Mohammed 1st, Oujda, Morocco.

Address correspondence to: Hanane Latrech, Email: hlatrech@hotmail.fr

Manuscript submitted: June 10, 2023; Resubmitted: August 17, 2023; Accepted: September 1, 2023

■ Abstract

Background: The closed loop insulin pump has significantly transformed the management of type 1 diabetes since its introduction. Several recent studies have examined the effects of Ramadan fasting on individuals with type 1 diabetes who use closed-loop insulin pumps. These studies have demonstrated that fasting throughout Ramadan leads to an increase in the amount of time spent within the target blood glucose range, while also reducing the occurrence of both hypoglycemia and hyperglycemia. Additionally, fasting has been found to enhance safety and flexibility in managing diabetes during this period. Objective: This study aims to assess the efficacy, safety, and patient satisfaction of the MiniMedTM 780G advanced hybrid closed loop system in managing glycemic control among individuals with Type 1 diabetes throughout the period of Ramadan fasting. Case presentations: Two cases of type 1 diabetes patients who underwent treatment with the MiniMedTM 780G advanced hybrid closed loop device and observed fasting during the month of Ramadan in 2023 were documented. The glycemic target was established at a level of 110 mg/dl, with the potential implementation of a temporary objective if blood glucose levels fell below 100 mg/dl. These parameters enabled the maintenance of optimum glycemic control, with a time in range exceeding 85%, while avoiding an increase in hypoglycemia occurrences and resulting in higher levels of satisfaction. Conclusion: The concept of a closed loop refers to a system in which the output of a process is sent back into the system as input, The utilisation of insulin pump therapy has demonstrated reliability and efficacy in individuals with type 1 diabetes mellitus who observe Ramadan fasting, provided that it is employed accurately. Enabling appropriate glycemic management to enhance quality of life. We present the initial assessment of glycemic control and satisfaction throughout the fasting period of Ramadan using an advanced hybrid closed loop approach, based on the current body of knowledge.

Keywords: Type 1 diabetes-advanced hybrid closedloop system-Ramadan Fasting-TIR-Satisfaction

1. Introduction

he month of Ramadan, regarded as sacred in the Islamic faith, is observed during the ninth lunar month of the Islamic calendar and typically spans a duration of 29 to 30 days. The act of fasting during the month of Ramadan is considered to be one of the fundamental pillars of the Islamic faith. The practise entails abstaining from food, water consumption, and sexual activity from the time of sunrise until sunset. The duration of this period varies between 10 to 20 hours, depending on factors such as geographical location and the specific fasting season [1]. The obligation to observe this fast is incumbent upon all adult Muslims who have reached the age of puberty. Nevertheless, certain

categories of individuals are exempted from this obligation, including those who suffer from medical conditions, such as individuals diagnosed with type 1 diabetic mellitus (T1DM) [1]. Owing to the metabolic characteristics of the disease, individuals with T1DM are categorised as being at a significantly elevated risk of experiencing particular complications while observing the Ramadan fast. This heightened risk is attributed to the increased occurrence of glycogenolysis, gluconeogenesis, and ketogenesis during this fasting period. Consequently, T1DM patients face potential hazards including hypoglycemia, dehydration, hyperglycemia, and even diabetic ketoacidosis (DKA) [2].

However, in spite of the religious and medical exemptions, a significant number of individuals with

T1DM choose to observe fasting throughout Ramadan without disclosing this to their healthcare provider. Surveys conducted globally have reported proportions as high as 20.2% [3, 4]. Therefore, it is recommended that physicians offer personalised care to patients with T1DM who express a desire to observe fasting throughout the month of Ramadan. This care should include a preeducation consultation specifically tailored for Ramadan, taking into account the patient's diabetes severity and associated risks. Additionally, an evaluation should be conducted to determine the patient's appropriateness for fasting [2]. At the conclusion of this consultation, modifications pertaining to type, dosage, and regimen of insulin are implemented, with a particular focus on the significance of self-monitoring blood glucose levels in order to mitigate glycemic abnormalities [1].

In recent years, a number of studies have been conducted to assess the effects of fasting on individuals with T1DM, specifically examining the safety considerations related with fasting throughout the holy month. Research findings indicate that a significant proportion of patients engage in fasting for a duration beyond 15 days, with over 60% of individuals fasting for the entirety of a month [5, 6].

The effects of Ramadan fasting have been examined in individuals with T1DM who are undergoing different treatment protocols. The study provided evidence that fasting while using insulin pumps resulted in a decreased likelihood of experiencing hypoglycemia during the fasting period and hyperglycemia caused by excessive nocturnal feeding, in comparison to fasting while using a multiple daily injection regimen. Patients utilising insulin pumps had enhanced glycemic control, satisfaction, and quality of life in the context of fasting [2]. Nevertheless, a further investigation that compared the two treatment regimens failed to identify any statistically significant disparity in the incidence of hypoglycemia and hyperglycemia when fasting [7].

It is imperative to emphasise that regardless of the treatment plan, diligent monitoring of blood glucose levels during the fasting period is essential. Previous research has documented glycemic variations, including asymptomatic hypoglycemia, in patients with T1DM who underwent continuous glucose monitoring [6]. Hence, the efficacy of continuous glucose monitoring (CGM) has been established in the identification of hypoglycemia tendencies and the mitigation of glycemic fluctuations during periods of fasting.

As a result of therapeutic advancements and the commercial availability of the artificial pancreas, a device that emulates the body's physiological processes by administering insulin based on real-time blood glucose levels, it appears that fasting may be a more viable option with reduced potential for consequences [8]. Several recent studies have examined the effects of Ramadan fasting on individuals with T1DM using he MiniMedTM 780G advanced hybrid closed loop system (MiniMedTM 780G AHCL). These studies have demonstrated an improvement in the duration of

Abrivations:							
MiniMedTM	MiniMedTM 780G advanced hybrid						
780G AHCL	closed-loop system						
T1DM	Type 1 Diabetes mellitus						
DKA	Diabetic ketoacidosis						
BMI	Body Mass Index						
ICR	insulin to carbohydrate ratio						
TIR	Time in Range						
TBR	Time below range						
TAR	Time above range						
GMI	Glucose Management Indicator						
DTSQ	Diabetes Treatment Satisfaction Questionnaire						
SPSS	Statistical Package for the Social Sciences						
CGM	Continuous Glucose Monitoring						
DBLHU	Diabeloop Highly Unstable Diabetes System						
DIDS	Diabetes Impact and Devices Satisfaction						

time spent within the target glucose range (referred to as time in range or TIR), accompanied by a reduction in both hypoglycemic and hyperglycemic episodes. Consequently, there was a notable enhancement in both the safety and flexibility experienced by the patients throughout the fasting period [8].

Based on the available information in English literature, there are only two published articles that have documented the performance of the MiniMedTM 780G AHCL system in individuals diagnosed with T1DM during the observance of Ramadan [8, 9]. Therefore, in order to contribute to the current body of knowledge, we present our findings on the practise of fasting in adult individuals diagnosed with type 1 diabetes who were undergoing treatment with the MiniMedTM 780G AHCL system. Specifically, we examine the efficacy, safety, and level of satisfaction associated with this approach.

2. Patients and Methods

2.1. Study design

The present study is a prospective, descriptive, and analytical investigation undertaken inside the Endocrinology-Diabetology and Nutrition Department at the Mohammed VI University Hospital Centre in Oujda, located in the eastern region of Morocco. Both individuals possessed comprehensive medical records. The researchers gained approval from the ethics commission at the local level. The participants provided their informed consent for participation in the research project. (Figure 1).

2.2. Duration of the study

Two months; i.e. 4 weeks before the holy month of Ramadan and during the month of Ramadan.

2.3. Study population

Patients with T1DM meeting the inclusion criteria:

Inclusion criteria: Patients over 18 years of age, initially treated with insulin pump for at least 1 year (MiniMedTM 780G or MiniMedTM 640G) and who are put on MiniMedTM 780G AHCL system for at least 1 month before the beginning of Ramadan.

- Insulin requirements>8 U per day.
- Well-controlled patients (HbA1c<7.5 % without

- hypoglycemia).
- Patients who practice flexible insulin therapy.
- Voluntary patients who were able to follow the study protocol, and who gave their consent for participation in the study.

Exclusion criteria:

- Pregnancy.
- Honeymoon phase.
- Presence of complications; history of severe hypoglycemia and/or with impaired awareness, DKA within the last 6 months.
- Patients with poor glycemic control (HbA1c>7.5 %)

2.4. Study protocol

Our study consisted of two phases, before and during the month of Ramadan;

2.4.1. Before Ramadan

- *Education*: After inclusion, the medical staff met the patients to provide information and instructions for safe fasting, which consisted of:
- Clinical assessment: weight, Body Mass Index (BMI), food diary details(g/day).
- General revision of flexible insulin therapy: carbohydrate counting and insulin to carbohydrate ratio (ICR) adjustments.
- Nutrition Education during the month of Ramadan with test fasting days in order to better prepare patients for the continuous fasting days.
- It should be noted that no dietary restrictions were imposed and that the patients followed their family food habits during the month of Ramadan.
- Education and information on indications for ending their fast (Fasting should be stopped in case of: Hypoglycemia <70 mg/dl, hyperglycemia >250 mg/dl, signs of hypoglycemia or the patient is feeling unwell).

a. Patient instructions

- Patients were informed that attending information and education sessions was mandatory.
- The bolus must be administered before the meal.
- During the Iftar, if the meal is rich in fats, the patient would add 15 to 30 % of bolus after 1h30min of the first bolus if sensor blood glucose is higher than 150mg/dl, then the adjustment would be according to the glycemia.
- During fasting hours, patients switch to the temporary objective if glycemia is under 100 mg/dl, and they must avoid any important physical activity especially during the period just before Iftar.
- The patients must also perform 2 to 3 calibrations per day, and they should adhere to hypoglycemia and hyperglycemia alarms
- We recommend them to use the Smart-Guard during the whole study and to stay connected to the internet.
- Catheters must be changed every 2 days
- The patients have been informed that they must be available for further instructions.

b. Insulin pump settings

- At the beginning of the study, we have defined a

target of 100mg/dl and a duration of active insulin of 2h as recommended [8], these parameters were adjustable throughout the study.

2.4.2. During Ramadan

- Monitoring (data was reported on pre-established data sheets).
- Uploading of reports was done weekly during the study period.
- Adjustment of the ICR was based on the followup, either by face-to-face consultations or during teleconsultations.

2.5. Outcomes

The main aim of our study was to assess the management of blood sugar levels during the period of Ramadan in adult individuals with type 1 diabetes mellitus who were undergoing fasting, and who were being treated with the MiniMedTM 780G Advanced Hybrid Closed Loop (AHCL) system.

The secondary objectives of this study were to assess and compare various indicators of glycemic control before and during the holy month. These indicators included TIR, Time below Range (TBR), Time above Range (TAR), Glucose Management Indicator (GMI), coefficient of variation, total daily insulin dose, percentage of daily boluses, number of auto correction boluses, daily carbohydrate intake, ICR, number of days of complete fasting, incidence of hypoglycemia (defined as glycemia<70 mg/dl), severe hypoglycemia, DKA, weekly sensor wear, and weekly Smart Guard activation. An additional secondary objective of the study was to assess participants' satisfaction by employing the Diabetes Treatment Satisfaction Questionnaire (DTSQ). The Arabic-translated version of the questionnaire, validated by our medical team [10], was utilised for data collection in Morocco.

2.6. Statistical analysis

All analyses were performed with the Statistical Package for the Social Sciences (SPSS) version 21.0 software (IBM, Armonk, NY). The different data were distributed and presented as means.

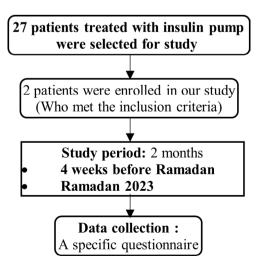


Figure 1: Study Protocol

3. Cases-presentation

Case 1

The patient under consideration is a 22-year-old female who has been diagnosed with type 1 autoimmune diabetes for the past 11 years. The individual in question was enrolled as a student at a university. The initial manifestation of diabetes in this case was DKA, which was subsequently managed using a normal treatment protocol. Subsequently, as a result of ongoing inadequate glycemic control over a span of 8 years since the onset of diabetes, the individual was brought to our medical facility. In order to address this issue, the patient's treatment approach was modified to include several daily injections along with self-monitoring of blood glucose levels. Additionally, the patient derived significant benefits from participating in an educational therapy programme. Hence, in order to achieve an ideal level of glycemic control, the implementation of flexible insulin therapy was recommended.

During the subsequent assessment, a continuous glucose monitoring was conducted. The patient exhibited signs of early-onset postprandial hypoglycemia, leading to the initiation of treatment with the MiniMedTM 640G insulin pump in 2021. The mean HbA1c level achieved using the insulin pump was 6.6±0.2%, with no instances of hypoglycemia seen. The patient was prescribed the MiniMedTM 780G AHCL system in April 2022 to enhance diabetes management. During the subsequent assessment, we observed a time in range above 70%, a coefficient of variation approximately around 28%, and a GMI of 6.6%.

In anticipation of the commencement of the sacred month, we conducted a series of fasting trials for a duration of one month. At the onset of the investigation, a glycemic target of 100 mg/dl was deemed suitable, along with an active insulin duration of 2 hours. During the period of testing, we saw a propensity towards hypoglycemia, prompting us to modify the goal value to 110 mg/dl and adjust the active insulin duration to 3 hours.

The mean TIR observed during the designated testing period was 89.5%, as indicated in Table 1. During the observance of Ramadan, our patient adhered to the practise of fasting for the duration of the month, with the exception of the days during which menstruation occurred. It is important to note that menstruation is recognised as a valid exemption from fasting for Muslim women, regardless of their state of health. The percentage of smart guard wear was 95%, with an average sensor glucose level of 138±38 mg/dl compared to 142±41 mg/dl, and a variability of 27.5% compared to 29% prior to the start of Ramadan (Table 1).

During the period of religious observance, a notable reduction was observed in the frequency of daily meals (1.9 meals per day compared to 3.4 meals per day) as well as the quantity of carbohydrates consumed per day (165±35g/day compared to 228±31g/day). The ICR had a modification during the initial week of Ramadan, decreasing from 11g/U (grammes per

unit) to 10g/U. However, the ratio of 11g/U was maintained for the Suhour meal. In the context of insulin requirements, it was observed that the total daily insulin dose decreased from 47.4 U/day to 38.2 U/day during the fasting phase. In terms of glycemic management, TIR during fasting exhibited a higher percentage of 87% compared to 82%, resulting in a decrease in the duration of hyperglycemia as indicated in Table 1. During the period of fasting, in accordance with medical guidelines, the average duration of temporary goal was seen to be 40 minutes per day. The patient had no signs of severe hypoglycemia or DKA. The fasting protocol was maintained throughout the duration of the trial.

The general satisfaction score, specifically measuring satisfaction with insulin pump treatment, was determined to be a perfect score of 36 out of 36. The rating for the perception of hyperglycemia and hypoglycemia sensations was 2 out of 6 and 0 out of 6, respectively.

Case 2

The second patient, a 26-year-old individual, was gainfully employed on a full-time basis within a corporate organisation. The patient has been undergoing follow-up for a period of six years due to the presence of autoimmune type 1 diabetes. The condition was initially detected following an episode of DKA, after which the patient was prescribed a regimen involving numerous daily injections. During the subsequent monitoring period, the patient had a high frequency of hypoglycemic episodes despite appropriate treatment modifications. Consequently, the patient was prescribed the MiniMedTM 640G device. The utilisation of an insulin pump effectively regulated diabetes, resulting in an average HbA1c level of 6.2±0.2 %, while successfully avoiding episodes of hypoglycemia. However, subsequent examination during the consultation revealed deficiencies in nutritional adjustments, leading to the patient receiving advantages from a flexible insulin therapy.

In February 2023, our patient was recommended the utilisation of a MiniMedTM 780G AHCL system in order to achieve optimal glycemic control and to explore the practise of fasting during the religious observance of Ramadan.

After the activation of Smart Guard, a period of one month transpired, during which we observed a TIR of 87%, with a mean sensor glucose level of 127±40 mg/dl. Similar to the first scenario, a preliminary assessment was conducted to evaluate the feasibility of observing fasting for the whole month of Ramadan. This assessment involved a two-day fasting period, during which the participants' active insulin duration was set at two hours and their glycemic target was established at 100 mg/dl. In the month of Ramadan, the percentage of sensor wear was recorded as 95%, accompanied by a mean blood glucose level of 126mg/dl. The coefficient of variation for blood glucose levels during this period

was found to be 29.1% compared to 31.5%. A high level of glycemic control was achieved, as evidenced by a TIR of 87% and a TBR of 9%. During the month of Ramadan, there was an observed increase in daily carbohydrate intake by 30g, whereas the carbohydrate ratio remained same. In the second week of fasting, an analysis of the glycemic profile led to the extension of the active insulin duration to 3 hours. Regarding the

interim goal, the mean duration each day throughout the month of Ramadan amounted to 4 hours and 54 minutes, as indicated in Table 1.

The global satisfaction score was determined to be a perfect 36 out of 36, indicating a high level of overall satisfaction. The perceived intensity of the experience of hyperglycemia and hypoglycemia was rated as 2 out of 6 and 1 out of 6, respectively.

Table 1: Table illustrating the different parameters of the Advanced hybrid closed loop insulin pump, before and during the holy month of Ramadan.

	Case 1			Case 2		
	Before	Days of fasting test	During Ramadan	Before	Days of fasting test	During Ramadan
Weight (Kg)	$69~\mathrm{kg}$	$69 \mathrm{\ kg}$	$67~\mathrm{kg}$	$57~\mathrm{kg}$	$57 \mathrm{\ kg}$	60 kg
Nb of fasting days	-	7	25	-	2	25
Smart Guard/week (%)	100%	-	95%	94%	-	99%
Sensor wear (%)	97%	-	95%	93%	-	95%
Average SG (mg/dL)	142 ± 41	-	138±38	127 ± 40	-	126 ± 37
GMI (%)	6.7%	-	6.6%	6.4%	-	6.3%
Coefficient of variation (%)	29%	-	27.5%	31.5%	-	29.1%
BG calibration (Nb/day)	2.6 ± 2.3	2	4.1 ± 3.2	2.6 ± 2.3	2	2.9±2.1
Total daily dose (U/day)	47.4	37.8	38.2	33.2	31.1	35.8
Bolus amount (U/day) (%)	32.8 (69%)	22.8 (60%)	23 (60%)	21.7 (65%)	20 (64%)	23.7 (66%)
Auto correction amount (U/day) (%)	6.7 (20%)	6.2 (27.4%)	4.4 (19%)	3.1 (14%)	5.8 (28%)	2.4 (10%)
Auto Basal/Basal amount (day) (%)	14.6 (31%)	15.07 (40%)	15.2 (40%)	11.5 (35%)	11.1 (36)	12.1 (34%)
Reservoir and set change (Nb of days)	3	3	3.7	3.1	-	3.2
Nb of meals per day	3.4	1.14	1.9	2.8	1.5	2.7
Carbohydrates (gr/day)	228±31	109.5	165 ± 35	171 ± 35	100	203±29
ICR (gr)	9 - 7.2 - 11	9 - 7.2 - 11	9.5 - 10 - 11	8.7-11-8.8	8-11-8.8	8-11-8.8
insulin sensitivity index	0.6	0.6	0.6	0.8	0.8	0.8
active insulin	2h	2h	3h	2h	2h	3h
TIR 70–180 mg/dL (%)	82%	89.5%	87%	87%	77.5~%	87%
TBR<70 mg/dL (%)	1%	0.2%	1%	2%	0.5 %	3%
TBR<54 mg/dL (%)	0%	0%	0%	1%	0 %	1%
TAR~180-250~mg/dL~(%)	15%	10%	11%	9%	20 %	9%
TAR>250 mg/dL (%)	2%	0%	1%	1%	2 %	0%
average hours of temporary objective (h/Day)		2h24min	40 min	_	5h	4h54min

Nb: Number; SG: Sensor Glucose; GMI: Glucose management indicator; BG: Blood Glucose; ICR: insulin to carb ratio; TIR: time in range; TBR: time below range; TAR: time above range

4. Discussion

TIDM is the most commonly observed endocrine disorder in the paediatric and teenage population. The occurrence of this phenomenon is experiencing an annual growth rate of 3 to 4%. The long-term maintenance of excellent glycemic control necessitates the implementation of specialised management techniques [11]. Currently, the insulin pump is considered the primary treatment for TIDM. Based on recent research findings, it has been observed that a mere 30% of patients are able to attain the specified aim even with the implementation of enhanced treatment [12]. From this perspective, the management of patients with T1DM has made substantial advancements in the past 15 years. These advancements include the introduction of several technologies, such as flash glycemic monitoring, CGM, and the more recent closed-loop insulin pump [12].

The closed-loop insulin pump is an innovative technology that utilises an algorithm for blood glucose control in conjunction with an external insulin pump and continuous glucose monitoring [13]. The algorithm has been designed to modify the administration of

insulin based on fluctuations in glycemic levels. It reduces insulin delivery when there is a perceived risk of hypoglycemia and increases delivery when hyperglycemia is detected [13].

The effects of Ramadan fasting have been examined in individuals with T1DM who were undergoing different treatment protocols. The literature has provided evidence that closed-loop systems enable fasting to be conducted in a manner that is both safe and efficient. This approach is associated with a reduced occurrence of hypoglycemia throughout the fasting period and a decrease in hyperglycemia after Iftar [8]. In the present investigation, the Ramadan fasting practise was assessed using the MiniMedTM 780G AHCL system. An improvement in glycemic control was observed during the duration of Ramadan fasting in comparison to the preceding month. The objective demonstration of this phenomenon is supported by a decrease in the GMI by 1% and a decrease in the rate of sensor glucose in both patients. These changes can be attributed to an improvement in the TIR accompanied by a decrease in the TAR, without a substantial rise in the TBR below 70 mg/dl and 54 mg/dl, as indicated in Table 1. These findings may provide reassurance to young individuals with type 1 diabetes, since they suggest that fasting throughout the holy month of Ramadan does not necessarily lead to severe hypoglycemia or DKA. The aforementioned issues are the primary impediments to fasting among individuals diagnosed with T1DM. In the course of our investigation, the individuals participating in our study did not experience any occurrences necessitating the cessation of fasting.

Additionally, patients often have a negative experience when they encounter hypoglycemia during the fasting period. This experience is typically accompanied by feelings of guilt, underestimate, and insecurity regarding future fasting [14]. The successful avoidance of this issue was achieved through the implementation of closed-loop fasting. This was substantiated by a randomised controlled trial involving 21 patients in each group. The trial specifically examined the effects of Ramadan fasting in patients utilising the MiniMedTM 780G AHCL system. The results demonstrated an enhancement in glycemic control, as evidenced by a decrease in GMI (6.4% vs. 6.6%), sensor glucose levels, and an increase in TIR. Notably, this improvement was achieved without an accompanying increase in hypoglycemic episodes. Furthermore, a statistically significant reduction in TAR was observed (p=0.007) [8].

The patients in our study mostly experienced hypoglycemic episodes shortly after consuming Suhoor, which were effectively resolved by adjusting the active insulin duration from 2 hours to 3 hours for both patients. Hyperglycemia episodes were observed to manifest either during sensor change intervals, ameliorated with manual correction boluses, or subsequent to the consumption of a high-fat meal at Iftar, coinciding with the conclusion of the active insulin duration. The second scenario was rectified with the administration of an additional bolus, constituting 10 to 20% of the first dose, at a time interval of 1 hour and 30 minutes to 2 hours following the Iftar meal. A same finding was reported in a parallel study, wherein elevated levels of sensor glucose were observed two hours after Iftar subsequent to the consumption of meals heavy in fat and protein. This effect was mitigated by administering an extra bolus of 15% within the time frame of 30 to 90 minutes post-meal [9]. Moreover, a study conducted in Egypt suggested a 34.4% augmentation in bolus dosage for patients exhibiting carbohydrate surplus [8]. Research has demonstrated that patients utilising the MiniMedTM 780G AHCL system and employing accurate carbohydrate counts exhibited superior glycemic control compared to patients who solely relied on the basic notification of their meals [15]. In our study, modifications for carbohydrate excess were not implemented due to the effective utilisation of flexible insulin therapy by our patients.

This therapeutic approach adequately accounts for all eaten carbohydrates, obviating the necessity for regular bolus supplementation.

The literature has already documented these glycemic excursions, leading to the recommendation of regularly monitoring blood glucose levels in the hours following Iftar in order to identify postprandial hyperglycemia [16]. It was also advised to postpone the Suhoor meal, which should consist of foods rich in dietary fibres, low glycemic index foods, and lean protein. Additionally, it is important to exercise discretion when administering insulin to minimise the fasting duration and prevent occurrences of hypoglycemia or hyperglycemia [17].

However, it should be noted that the enhancement of glycemic control does not always coincide with a rise in the overall insulin dosage, as has been shown in comparable research studies [8, 9]. In the initial case, it was observed that the overall insulin dosage, including the bolus and auto correction quantities, exhibited a drop during the period of Ramadan in comparison to the preceding month. This reduction might be attributed to a decrease in the daily consumption of carbohydrates. However, the second case demonstrated a rise in the overall insulin dosage, resulting in a decrease in the bolus dose. This can be attributed to a simultaneous increase in the consumption of carbohydrates. The existing literature has documented the discrepancy between insulin dosage and carbohydrate consumption. There exists a notable cultural diversity among individuals, even within the same family and region, with regards to the specific types and quantities of food consumed during Ramadan, as well as the timing of meal intake. This variation inevitably impacts the glycemic profile of patients [17].

The variation in daily carbohydrate consumption across individuals is also accountable for disparities in weight growth. Patients who consume a diet that is high in sugar or fried foods throughout the month of Ramadan tend to experience weight increase, whereas those who adhere to a healthy diet tend to lose weight [18]. In the second documented case, a weight rise of 3 kg was seen as a result of elevated carbohydrate consumption during the month of Ramadan (Table 1).

Current research has been placing emphasis on the examination of glycemic variability in individuals diagnosed with T1DM due to its significant correlation with glycemic management and the development of acute or chronic problems [19]. In the current investigation, it was observed that there was a decrease in the coefficient of variation, indicating a reduction in glycemic variability, in both patients during the month of Ramadan in comparison to the preceding month. This finding aligns with the results presented in previous investigations [8, 9].

Limited research has been conducted on the topic of satisfaction with insulin pump therapy, with a special emphasis on the closed-loop insulin pump technology. In the context of the present discussion, a scholarly publication authored by Delagenière*et al.*

[20] documented the assessment of user satisfaction with the Diabeloop Highly Unstable Diabetes System (DBLHU) by the utilisation of the DTSQ. This study found that participants reported higher levels of satisfaction with the DBLHU treatment compared to the insulin pump with predictive low glucose suspend system [20]. In a separate empirical investigation, Pinskeret al. [21] documented enhanced patient satisfaction among those receiving treatment using the Control IQ Technology System. This conclusion was drawn based on the analysis of data obtained from the Diabetes Impact and Devices Satisfaction (DIDS) Scale. Additionally, the researchers observed a decrease in the overall burden of diabetes. Within the current body of literature, our investigation did not yield any scholarly inquiries pertaining to the examination of satisfaction levels specifically during the month of Ramadan within the context of an advanced hybrid closed loop system. In this study, the Arabic-translated version of the DTSQ was utilised for data collection within our country. The present iteration underwent validation by our medical experts in the year 2021[10]. Despite the limited size of our sample, we have observed a higher level of satisfaction with the implementation of an advanced hybrid closedloop system in comparison to the previous insulin pump. Additionally, a decline in the impression of both hypoglycemia and hyperglycemia was seen.

This study presents the initial encounter with managing fasting practises during the holy month of Ramadan using the MiniMedTM 780G AHCL device inside our nation. Our study findings provide evidence supporting the effectiveness and safety of utilising the closed-loop insulin pump in ensuring adequate glycemic control throughout the period of Ramadan fasting. Furthermore, we placed significant emphasis on the enhancement of treatment satisfaction associated with the utilisation of this particular insulin pump.

The results of this study may serve as an encouragement for young individuals diagnosed with type 1 diabetes to observe fasting throughout the holy month of Ramadan, as they can do so without any concern for experiencing severe hypoglycemia or DKA, which are commonly perceived as major challenges associated with fasting. However, it is important for patients who fast throughout Ramadan to get appropriate preparation and be closely monitored by experienced diabetologists in order to ensure a safe

and effective fasting experience.

Given the aforementioned circumstances, we propose that individuals who are proficiently adhering to flexible insulin therapy should consider the following course of action:

The recommended glycemic target is 110 mg/dl.

The active insulin has a duration of 3 hours.

The temporary purpose is to switch when the sensor glucose level falls below 100 mg/dl.

The limitations of our study are mostly attributed to the monocentric nature of the research design and the relatively limited sample size of patients utilising closed-loop insulin pump technology. The limited availability of closed-loop insulin pumps in our developing country can be attributed to the substantial and enduring expenses associated with the equipment, as well as the inadequate access and coverage provided by medical insurance companies.

5. Conclusion

The utilisation of a closed loop insulin pump has been found to enhance glycemic control and increase satisfaction among individuals observing fasting during the holy month of Ramadan. However, it is imperative that the management of the insulin pump is overseen by a proficient medical team. This team should possess the ability to tailor the educational guidance provided and adjust the insulin pump settings according to the patient's specific lifestyle and dietary practises. This approach ensures the utmost safety and well-being of individuals during their fasting period.

Author Contribution: Dr Najoua Messaoudi and Dr Nisrine Bouichrat are the First co-authors, they wrote the manuscript, Dr Imane Assarrar and Dr Nabila Zeryouh helped in writing the manuscript and literature review. Professor Siham Rouf and Professor Hanane Latrech supervised and participated in the writing and revised the final manuscript, All the authors approved the final draft of the manuscript.

Funding: The authors did not receive any funding for this paper

Conflicts of Interest: The authors declare that they have no conflicts of interest.

■ Reference

- Hassanein M, Afandi B, Ahmedani MY, Alamoudi RM, Alawadi F, Bajaj HS, et al. Diabetes and Ramadan: practical guidelines 2021. *Diabetes* research and clinical practice 2022. 185:109185.
- 2. Al-Arouj M, Assaad-Khalil S, Buse J, Fahdil I, Fahmy M, Hafez S, et al. Recommendations for management of diabetes during Ramadan: update 2010. *Diabetes Care* 2010. 33(8):1895-902.
- 3. Salti I, Bénard E, Detournay B, Bianchi-Biscay
- M, Le Brigand C, Voinet C, et al. A population-based study of diabetes and its characteristics during the fasting month of Ramadan in 13 countries: results of the epidemiology of diabetes and Ramadan 1422/2001 (EPIDIAR) study. *Diabetes Care* 2004. 27(10):2306-11.
- 4. Hassanein M, Alamoudi RM, Kallash MA, Aljohani NJ, Alfadhli EM, Tony LE, et al. Ramadan fasting in people with type 1 diabetes

- during COVID-19 pandemic: The DaR Global survey. *Diabetes Res Clin Pract* 2021. 172:108626.
- 5. Deeb A, Al Qahtani N, Akle M, Singh H, Assadi R, Attia S, et al. Attitude, complications, ability of fasting and glycemic control in fasting Ramadan by children and adolescents with type 1 diabetes mellitus. *Diabetes Res Clin Pract* 2017. 126:10-5.
- 6. Kaplan W, Afandi B. Blood glucose fluctuation during Ramadan fasting in adolescents with type 1 diabetes: findings of continuous glucose monitoring. *Diabetes Care* 2015. 38(10):e162-e3.
- Mohamed K, Al-Abdulrazzaq D, Fayed A, El Busairi E, Al Shawaf F, Abdul-Rasoul M, et al. Fasting during the holy month of Ramadan among older children and adolescents with type 1 diabetes in Kuwait. J Pediatr Endocrinol Metab 2019. 32(8):843-9.
- 8. Elbarbary NS, Ismail EAR. Glycemic control during Ramadan fasting in adolescents and young adults with type 1 diabetes on MiniMedTM 780G advanced hybrid closed-loop system: A randomized controlled trial. *Diabetes Res Clin Pract* 2022. 191:110045.
- 9. Wannes S, Al Qusayer D, El Abed S, Ben Fredj M. Insulin pump therapy and glucose control during Ramadan fasting in an adolescent with type 1 diabetes: from an open-loop sensor-augmented pump therapy with predictive low-glucose management to an advanced hybrid closed-loop system. Acta Diabetol 2023. 60(6):851-5.
- 10. Messaoudi N, Tahri A, Assarar I, Bouichrat N, Derkaoui N, Bouazzaoui MA, et al. Does the Insulin Pump Improve Satisfaction and Glycaemic Control in Moroccan Patients with Type 1 Diabetes? Rev Diabet Stud 2023. 19(1):8-13.
- 11. Briet C, Piffaretti C, Fosse S, Denis P, Allix I, Campagna A, et al. Épidémiologie du diabète de type 1 et de ses complications. *Revue du Praticien* (*La*) 2018. 68:607-10.
- 12. Foster NC, Beck RW, Miller KM, Clements MA, Rickels MR, DiMeglio LA, et al. State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016-2018. *Diabetes Technol Ther* 2019. 21(2):66-72.
- 13. Maahs DM, Buckingham BA, Castle JR, Cinar A, Damiano ER, Dassau E, et al. Outcome Measures for Artificial Pancreas Clinical Trials: A Consensus Report. *Diabetes Care* 2016. 39(7):1175-9.
- **14. Elbarbary NS.** Effectiveness of the low-glucose suspend feature of insulin pump during fasting during Ramadan in type 1 diabetes mellitus. *Diabetes Metab Res Rev* 2016. 32(6):623-33.
- 15. Petrovski G, Campbell J, Pasha M, Day E, Hussain K, Khalifa A, et al. Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents With Type 1 Diabetes Using the MiniMed 780G Advanced Hybrid Closed Loop System: A Randomized Controlled Trial Comparing Glucose Control. *Diabetes Care*

- 2023. 46(3):544-50.
- 16. Smart CE, Annan F, Higgins LA, Jelleryd E, Lopez M, Acerini CL. ISPAD Clinical Practice Consensus Guidelines 2018: Nutritional management in children and adolescents with diabetes. *Pediatr Diabetes* 2018. 19 Suppl 27:136-54.
- 17. Alamoudi R, Alsubaiee M, Alqarni A, Aljaser S, Saleh Y, Salam A, et al. Attitudes and habits of patients with type 1 diabetes during fasting Ramadan. *J Clin Transl Endocrinol* 2018. 14:1-4.
- 18. Zabeen B, Tayyeb S, Benarjee B, Baki A, Nahar J, Mohsin F, et al. Fasting during Ramadan in adolescents with diabetes. *Indian J Endocrinol Metab* 2014. 18(1):44-7.
- 19. Saadane I, Ali T, El-Laboudi A, Lessan N. Ramadan fasting in insulin-treated patients is associated with potentially unfavourable changes in glucose metrics: A flash glucose monitoring (FGM) study. *Diabetes Res Clin Pract* 2021. 172:108592.
- 20. Delagenière J, Schwartz C, Doron M, Huneker E, Franc S, Charpentier G, et al. Prospective analysis of satisfaction and usability of closed-loop Diabeloop DBLHU treatment in patients with highly unstable type 1 diabetes. *Acta Diabetol* 2021. 58(12):1709-11.
- 21. Pinsker JE, Müller L, Constantin A, Leas S, Manning M, McElwee Malloy M, et al. Real-World Patient-Reported Outcomes and Glycemic Results with Initiation of Control-IQ Technology. *Diabetes Technol Ther* 2021. 23(2):120-7.