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The Utility of Flash Glucose Monitoring for Patients with Type 1 Diabetes Mellitus during Fasting in Ramadan

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Abstract

Aims

The study aimed to assess the effectiveness of the Flash Glucose Monitor (FGM) in empowering patients with Type 1 Diabetes Mellitus (T1DM) to fast safely during the month of Ramadan.

Methods

In this prospective interventional study, eligible adult patients with T1DM were monitored with FGM and completed a survey after Ramadan. Time in range, glucose variability, changes in HbA1c, and renal function was evaluated. IRB approval and informed consent were acquired prior to the study. For data analysis (SPSS) Version 25 was used.

Results

The study included 8 adults (5 females, 3 males). The use of FGM enabled 25% of patients who were not able to fast in the previous year to fast in the current year.The median frequency of hypoglycemic episodes increased during Ramadan from 8 to 24 (p-value 0.049), however. Glucose variability during Ramadan was reduced by 4.05 ± 7.00 % but was not significant (p-value 0.17). The time in range before Ramadan was 51.00% ±10.75, during Ramadan was 53.42% ±14.83,and post-Ramadan was 55.85%± 10. HbA1cand creatinine did not change before and after Ramadan, (p-values of 0.465 and 0.315 respectively) indicating that glycemic control and renal function were maintained.

Conclusion

Active glucose monitoring using FGM coupled withstructured pre-Ramadan counseling and patient education aids in empowering patient to fast safely and maintain glycemic control during month of Ramadan and avoid complications including DKA and severe hypoglycemia.

Keywords: Diabetes Mellitus; Flash glucose monitoring; Fasting, Ramadan; Time in Range.

Introduction

Ramadan is the ninth month of the Islamic calendar in which Muslims are obligated to fast from dawn to dusk; the duration of fasting is dependent on the geographic location. In some parts of the world, daylight can last up to 20 hours in the summer. [1] Although it is an obligation for Muslims to fast, patients with chronic illnesses such as end-stage renal disease, congestive heart failure, uncontrolled type 1 diabetes mellitus (T1DM) are excused from fasting. However, despite their existing health conditions, some people insist on fasting [1].

Fasting Muslims with beginning of Ramadan. This alteration is associated with continuing changes in the rhythm and magnitude of fluctuations in various homeostatic and endocrine processes. In addition to sleeping patterns being altered during Ramadan, several circadian rhythm changes occur such as changes in body temperature and cortisol levels [2].

A pilot study conducted in Saudi Arabia found wide fluctuation of glucose levels between fasting and eating hours amongst patients with uncontrolled T1DM who fast during Ramadan, displaying a greater tendency toward hyperglycemia[3].

A cross sectional study revealed that approximately three quarters of all at-risk patients understand that fasting imposes a risk. Regardless, only 49.1% of participants had consulted with a healthcare professional of their plan/intention to fast and only 38.1% of participants monitor blood glucose levels throughout the month"[4]. "The frequency of diabetes complications including hypoglycemic-hyperglycemic episodes and diabetic ketoacidosis needs to be monitored and maintained at a minimal level during fasting in Ramadan. Levels of LDL need to be reduced improving the HDL levels at the same time. In order to achieve this interconnected etiology patient education and early treatment adjustment especially prior to the month of Ramadan is recommended[4- 6].

Healthcare workers and the patients in the frontlines must be empowered with appropriate information".[7]"Risk profiling,

dietary education, avoiding excessive physical activity during fasting, regular blood glucose monitoring, and intervention with adjustment of medications are recommended for DM patients who fast during Ramadan [8, 9].

By Islamic rules and medical recommendations patients with T1DM, particularly those with uncontrolled disease, are labelled as a high-risk group for Ramadan fasting and are exempt from fasting"[1]: however, the majority of them insist on fasting. "The Epidemiology of Diabetes and Ramadan (EPIDIAR) study found that 42.8% of patients with T1DM fasted for at least 15 days during Ramadan". [10] Many studies including a prospective case control study described the fact that when correct dietary and medication guidance was used, it was safe for patient with diabetes to fast in Ramadan [11, 12].

A prospective study conducted by Bailey et al., 2015 showed that compared to capillary (blood glucose) BG reference values, interstitial glucose measurements with the use of FreeStyleLibre system was found to be accurate; withprecision remaining stable over 2 weeks of use and unaffected by patient characteristics"[15]."The utilization of FreeStyleLibre has added benefits in patients with co morbid condition e.g. chronic kidney disease.Another prospective interventional study showed that, there was no worsening of HBA1c and renal function in patients with diabetes and CKD-stage 3 who fasted during Ramadan under close supervision and adequate diabetes care[16].

Amongst patients with diabetes, 80% of them fasted when physicians advise them not to". [17]Hence using FGM technology will allow patients to monitor their glucose level effectively and allows for adjustments to insulin doses to ensure their safety.

The use of a glucometer, a conventional method of glucose monitoring, gives only snapshots for glucose levels during the day; however, the real variability of glucose levels during fasting is not shown[13,14].

The present study aims to examine glucose level fluctuations during Ramadan fasting in patients with T1DM using flash glucose monitoring. This is the first study to our knowledge assessing the effectiveness of technology of flash glucose monitoring in the Kingdom of Bahrain in enabling patients with type 1 diabetes to fast safely.

Material and Methods

Study Design and population

The study was designed as a prospective interventional study that was conducted at the endocrinology and diabetes clinic at a tertiary care university hospital at the Kingdom of Bahrain. The hospital had recently disseminated FGM to all patients with T1DM. Inclusion criteria: Adult patients age 18 and above with T1DM who were eligible to fast according to risk stratification adopted by Diabetes and Ramadan (DAR guidelines)[18]. Exclusion Criteria: Patients with type 2 diabetes mellitus, pediatrics patients (<18 years old), uncontrolled T1DM (HBA1C > 8.5%)(69mmol/mol) and those who were at very high risk for fasting according to DAR guidelines including one or more of the following:

- History of Severe hypoglycemia and episode of unexplained DKA 3 months prior to Ramadan
- Previous History of hypoglycemia unawareness
- Pregnancy
- Patient with chronic kidney disease stage 4&5 OR onChronic dialysis
- Patients with advanced macrovascular complications

The primary outcomeswere to assess the effectiveness of FGM among patients with T1DM fasting in Ramadan by measuring the incidence of hypoglycemia (defined as blood glucose level below 3.9 mmol/L), hyperglycemia (defined as the blood glucose level above 10 mmol/L), DKA, emergency room visits, hospital admissions, clinic walk-in visit and the ability to fast during the month of Ramadan (by measuring the number of days a patient fasted in comparison to the days fasted in the previous year).It also included effect on HbA1c and renal function.Additionally, the evaluation included assessing the frequency of deciding to break their fast and assessment of medication adherence and lifestyle during Ramadan.

Study Protocol

All patients were on multiple daily insulin injections (MDI), and had individualized written instructions to insulin doses during fasting in Ramadan. All participants attended a structured online educational session two weeks before Ramadan. The session included guidance on the self-adjustment of insulin dosing during Ramadan and guidance on when a patient must break his/her fast due to hyper or hypoglycemia. In addition to recommendations on diet and exercises recommended by the DAR guidelines[18]. The session was followed by providing written instructions.

During non-fasting periods, the patients were allowed to have their usual food, basedon physician's advice.Blood samples were collected two weeks prior to Ramadan and two weeks after Ramadan. Patients were asked to fill an online questionnaire to report information such as visits to physicians at health center or endocrinology clinic and ER visits, physical activity, self-reporting of adherence to diet and medication, the number of days they were able to fast in the current year and in the previous year and rates of self-reported hyperglycemia and hypoglycemia. Evidence of any ER attendance was reviewed through the electronic health records at the end of study.

Biochemical analysis

All patients had blood samples two weeks prior to, and two weeks after Ramadan; after a minimum of an 8-hour overnight fast. Blood glucose, glycosylated hemoglobin (HbA1c) and renal function were measured.

Ethical approval

The study was approved by the King Hamad University Hospital Institutional Review Board. Patients signed an informed consent form prior to participating in the study.

Results

A total of 11 patients were eligible for the study, however, 3 patients were excluded due to irregular scanning and not responding to survey questionnaire. One participant responded to survey however didn't use FGM. All participants were adult patients above 18 years of age with well-controlled T1DM without complications who insisted to fast in Ramadan.

Survey responses specific to FGM

All patients reported adherence with medication instructions and five patients reported adherence to dietary instructions according to DAR guidelines.Reasons for exceptions of non-adherence with diet were due to their preference to eat with family and their likeliness for traditional food. All patients reported that the FGM monitoring helped them to fast safely during Ramadan. None of the patients had any major adverse reaction; one patient reported redness after removal of sensor and one other patient reported pain on applying the sensor. Four patients exclusively monitored their glucose withFGM, and four patients relied on both FGM and capillary glucose monitoring during the study. The details of response can be found in Table-1

FGM was usually used by all the patients during the study with a median frequency of 10 and IQR (Interquartile range) of (6.5 – 12.5). The lowest level of glucose in the study group during Ramadan was 51.64 ±14.24 and the highest level of glucose was 308.57 ± 44.16.(Figure 1 and 2)

Table1: Survey Results	
Age (Mean, SD)	30.28 ± 4.02
Frequency Table	
Gender (Female: Males)	2:6
Age Range	
18-30 years	5
31-45 years	3
Did you fast last Year 2019?	
Yes	6 (75%)
No	2 (25%)
How many days were you able to fast in Ramadan in the previous year?	
Not able to fast at all	2
< 10	1
20-Oct	2
Full	3
How many days were you able to fast in Ramadan in the current year?	
<10	3
20-Oct	1
21-30	1
Full	3
Did you break your fast due to Hyperglycemia? (current year)	
Yes	2(25%)
No	6(75%)
Did you break your fast due to Hypoglycemia? (current year)	
Yes	5 (62.5%)
No	3 (37.5 %)
Did you break your fasting in the current year due reason other than Hypoglycemia or Hyperglycemia?	
Yes	3 (37.5%)
No	5 (62.5%)
Did you have any episode of Hypoglycemia in the current year while fasting in Ramadan?	
Yes	6 (75%)
No	2 (25%)
During fasting in Ramadan, have you felt symptoms of hypoglycemia: palpitation, Headache, Tiredness, Sweating?	
Yes	7(87.5%)
No	1 (12.5%)
Did you have and episodes of Hyperglycemia in the current year while fasting in Ramadan?	
Yes	6 (75%)
No	2 (25%)
Did you have any symptoms of Hyperglycemia: Tiredness, Polyuria, Thirst, blurred vision?	
Yes	5 (62.5%)
No	3 (37.5%)
Did you need to seek health care facility while fasting this year due to blood glucose level?	
Yes	1 (visited Endocrine clinic only once for correction of insulin dose)
No	7
Did you engage in regular exercise during month of Ramadan?	
Yes	4 (50%)
No	4 (50%)
Did you adjust dose of insulin according to FGM reading?	
Yes	4 (50%)
No	4 (50%)

Table 2: Glucose variability according to data obtained from FGM download before, during and after Ramadan		
	Mean difference	P value (Paired sample T –test)
Glucose Variability		
T0- T1	- (4.05 ± 7.00)	0.17
T1-T2	(2.00 ± 4.14)	0.24
T0- T2	- (2.05 ± 7.75)	0.5

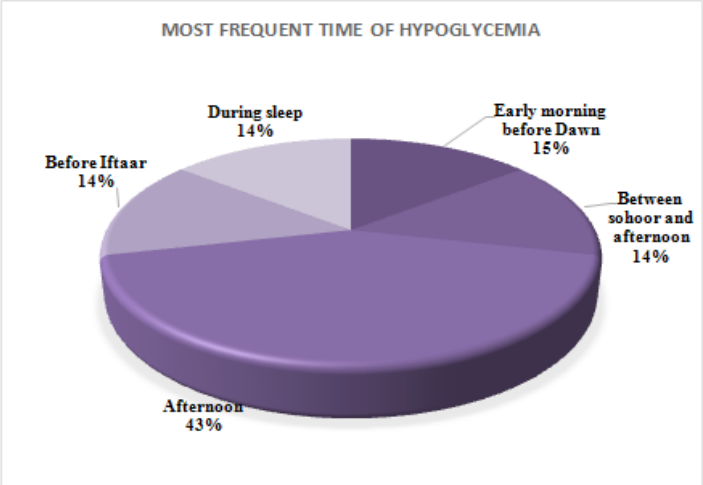

Figure 1: Frequency of self-reporting of most common time for hypoglycemia in study participants.

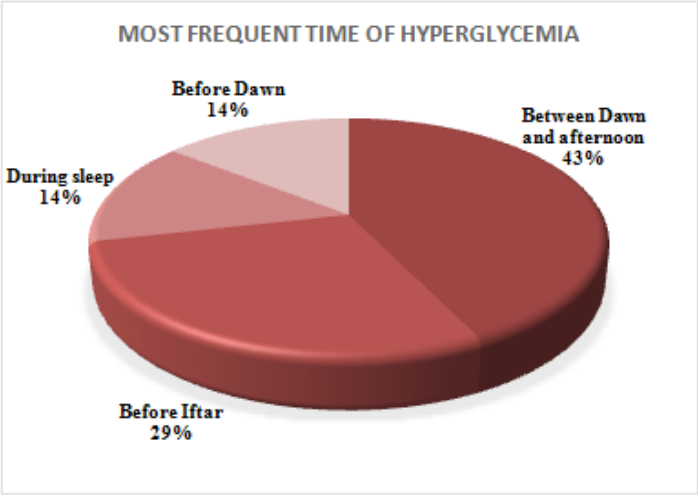

Figure 2: Frequency of self-reporting of most common time for hyperglycemia in study participants

FGM Scan Data Results

The mean HbA1c level prior to Ramadan was 7.01 ± 0.81 and the mean HbA1c level after Ramadan was 7.21 ± 12.8. With a mean difference of 0.20 ±0.67 (p-value 0.465).The difference was not significant indicating that the FGM effectively aided tomaintain glycemic control during fasting in Ramadan.The mean creatinine levels prior to Ramadan were 77.45 micromol/L± 15.48 and two weeks post-Ramadan was 74.72 micormol/L± 13.19. There was a mean decrease of 2.73 micormol/L± 6.58 in creatinine level; however this decrease was not significant.(p-value 0.315).

The median frequency of hypoglycemic episodes increased during Ramadan from 8 (IQR: 5, 23.5) to 24 (IQR: 8, 40) (p-value0.049). The frequency of hypoglycemic episode dropped to 9 (IQR: 6, 24) 2 weeks post Ramadan. This decrease in frequency of hypoglycemic episodes two weeks post Ramadan was not statistically significant (p-value 0.258). There was no statistical

difference in frequency of hypoglycemic index 2 weeks prior and 2 weeks post Ramadan indicating the merits of FGM in monitoring and taking measures promptly.

The median frequency of hyperglycemic episodes increased during Ramadan from 0 (IQR: 0, 4.5) to 4 (IQR: 0, 14.5)(P value 0.08). The frequency of hyperglycemic episode dropped to 1 (IQR: 0, 3.5) 2 weeks post Ramadan (P value 0.16).. Neither of the changes was statistically significant indicating that FGM helped to monitor and take measures promptly.

Glucose variability decreased in the study group during Ramadan with a decrease of 4.05 ± 7.00 %. Two weeks after Ramadan glucose variability increase by 2.00 ± 4.14 %. However, these changes were not statistically significant. (Figure 3,Table 2)

Time in range for normal glucose levels

There was no significant difference in the time in rangefor glucose values (set as glucose target of 70-180 mg/dl) during the study period, hence indicating that FGM helped in maintaining glucose control during fasting in Ramadan. (Figure 4)

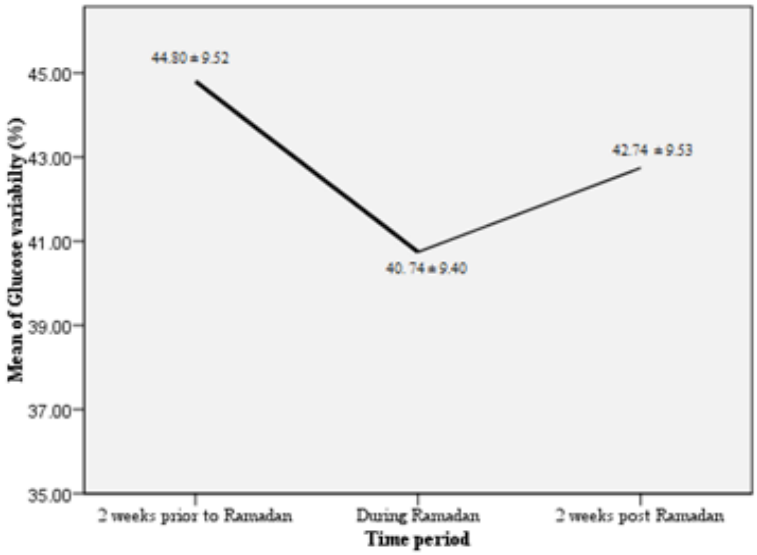

Figure 3: Glucose variability before, during and after Ramadan according to data downloaded from FGM

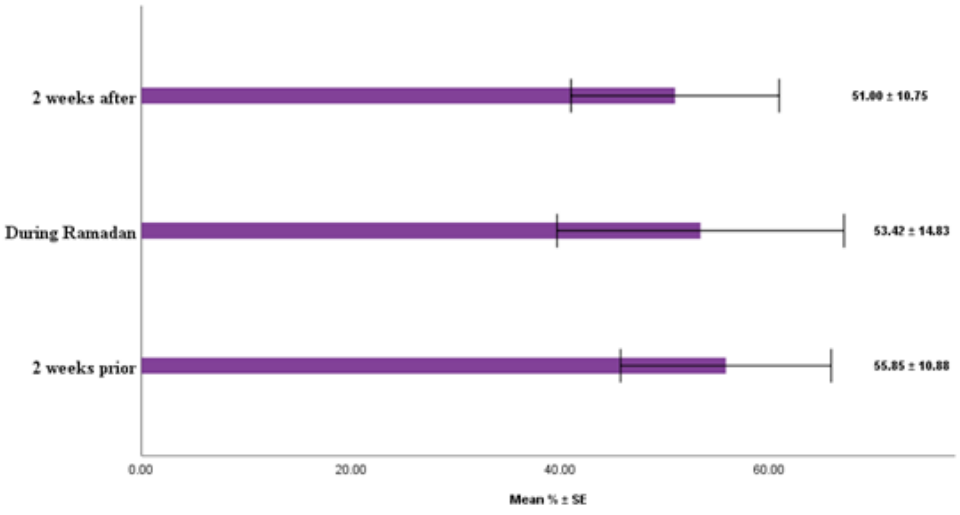

Figure 4: Time in range before, during and after Ramadan according to data downloaded from FGM

Discussion

Glucose control becomes a challenge due to risk of hypo and hyperglycemias and the fact that that meal timings vary. This challenge is even greater for patients with T1DM, but they often insist to fast as they do not want to feel isolated from the rest of the population.

A study focusing on T1DM patients provided with Ramadan-focused education,(including effects of fasting on their glucose blood glucose and other health parameters) flash glucose monitoring, dietary advice and treatment adjustment showed an improvement in glycemic control without an increase in hypoglycemia, biometric or metabolic parameters [19]. This is the first study in Kingdom of Bahrain to know effectiveness of utilization of FGM in patients with T1DM who are fasting in Ramadan.

Growth hormone, cortisone and catecholamines are released as stress response during fasting hours'[6] which are one of possibility of hyperglycemic episodes encountered in our study. However hypoglycemic episodes were higher than hyperglycemic episodes during month of Ramadan which was seen contrary to prospective pilot study conducted amongst patients with T1DM where hyperglycemic episodes were found to be higher than hypoglycaemic episodes [6].

Hyperglycaemic episodes were mainly between dawn and afternoon and decreasing thereafter (this was mainly due to heavy meals overnight mainly suhoor. 5 (62.5%) of participants experienced symptomatic hyperglycemia remaining 3(37.5%) were asymptomatic. However only 2 (25%) broke the fast amongst the patients who experienced hyperglycemia.

Accordingly, hypoglycaemic episodes were mainly found to be highest in afternoon period mainly due to absence of food for a long period (fasting was for 14.5 hours a day). 14% experienced hypoglycemic episodes during non-fasting hours which can be mainly attributed to insulin overdose or physical activity (50% participants were involved in physical activity). Amongst participants, 7 of patients (87.5%) experienced symptomatic hypoglycemia however remaining 1(12.5%) who didn't have any symptoms were aided by use of FGM for early detection of hypoglycemia timely. Therefore, FGM helped in allowing patients to detect hypoglycemia during fasting and react to it appropriately.

Fasting during Ramadan provides a challenge for physicians as shown in a population-based, retrospective, study and there is a need to provide intensive education prior and a close monitoring of blood glucose [10]. A Prospective observational study revealed that in Middle East and North Africa region further patient education is required ,and the support of International Diabetes Federation (IDF) and Diabetes and Ramadan (DAR) International Alliance Guideline that recommend treatment adjustments pre-Ramadan for Muslims who choose to fast[20]. DAR-MENA an observational prospective study revealed that almost half of patients with T1DM fasted for the full 30 days of Ramadan despite the risks associated with fasting with no significant change in hypoglycemia events and an improved glycemic control emphasizing the need for T1DM patients to work closely with their healthcare practitioner to ensure reduction of risk of complications.It is important that those who insist on fasting work closely with their healthcare practitioner to avoid any complications [21].

A prospective study indicated that DAFNE structured education enhanced quality of fasting and overall well-being in patients with T1DM[22]. These benefits are not limited for T1DM patients only. Another study showed structured education with adjustment of the dose of glucose lowering medication alongside use of the FGMS can effectively mitigate the increased risk of hypoglycemia in patients with T2DM on multiple glucose-lowering therapies who fast during Ramadan[23].COVID -19 pandemic has been taken into consideration in a cohort study which showed that T1DM patients aged of 18 years or above who decided not to fast during pandemic; which highlights the need for Ramadan focused diabetes education to improve glucose control and prevent complications during fasting [24].

All patients were provided with a structured educational session regarding diet and insulin adjustment.57% of patients required adjustment of insulin as compared to 63% patients as reported in another study [19].Participants were empowered to do it by themselves and only one patient (14%) visited the endocrine clinic once for the same purpose. No single episode of hyperglycemia was associated with ketoacidosis in the current study indicating effectiveness of Pre-Ramadan educationalsession and the use of FGMin provision of the needed guidance.

A prospective pilot study was conducted amongst patients with T1DM using FGM revealed safety of fasting with no life threatening events like DKA and severe hypoglycaemia encountered [6] which was the case in our study as well where there were no reported cses of DKA or severe hypoglycemia. Another observational prospective study conducted in the United Arab of Emirates reported that patients with diabetes can fast safely during Ramadan as no life-threatening events occur, such as severe hypoglycemia and diabetic ketoacidosis (DKA). In this study, participants not only broke the fast for diabetes-related issues like hypoglycemia and hyperglycemia, but also for other reasons such as menses, sickness, and travelling [25].A prospective study conducted on Patient with Type 2 Diabetes mellitus concluded that structured education with adjustment of the dose of antiglycemic medication alongside use of the FGM can effectively alleviate the increased risk of hypoglycaemia [23].

In Our study glucose variability reduced during month of Ramadan as compared to pre and post.However change was not significant. The median frequency of hypoglycaemic episodes increased during Ramadan however the increase was not found to be statistically significant similar to another study [19]. Mean HbA1c levels were not significantly changed post compared to pre-Ramadan indicating effectiveness of usage of FGM in maintaining glycemic controlduring fasting month,however it was contrary to another study that showed significant reduction

in HbA1c post Ramadan [19]. Majority patients fasted for more than half of month. 3(37.5%) were able to fast throughout month. 2 patients (25%) were able to fast for more than half (14.2% fasted for 21-30 days and 14.2% for 10-20 days).

Three participants (37.5%) were able to fast for less than 10 days. Two participants (25%) who were not able to fast in the previous year was able to fast in the current year during this study.

We concluded that active glucose monitoring using FGM coupled with pre-Ramadan structured counselling and patient education aids in empowering patient to fast safely and maintain glycemic control during month of Ramadan and avoid complications including DKA and severe hypoglycemia, hospital admissions or ER visits.FGM effectively aided in maintaining glycemic control in adult patients with T1DM during the fasting in Ramadan.FGM was effective as participants felt more empowered to fast and to break the fast if needed.

Limitations of study included small number of sample size. It reflects the care provided at a tertiary care university hospital and did not include a control group. Further studies of larger size and including more samples of participants are needed to validate the results and perhaps show more significant improvement in outcomes not seen in this study such as in improving HbA1c, time in range and glucose variability. Our study primarily included controlled T1DM patients, in future a study involving uncontrolled T1DM patients who insist to fast can be performed for same purpose.

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Declaration

The study was approved by the King Hamad University Hospital Institutional Review Board. Patients signed an informed consent form prior to participating in the study.

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