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# The use of Free Style Libre Continues Glucose Monitoring (FSL-CGM) to monitor the impact of Ramadan fasting on glycemic changes and kidney function in high-risk patients with diabetes and chronic kidney disease stage 3 under optimal diabetes care

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ABSTRACT

*Aim:* To understand the risk of hypoglycaemia during Ramadan fasting by use of CGM, as well as to observe the Glycemic control and renal functions in patients with diabetes and chronic kidney disease stage 3 (CKD-3).

*Method:* A prospective interventional study conducted in the Dubai Hospital, a tertiary care centre in the United Arab Emirates, during the month of Ramadan 1437 AH (Hijri), which corresponded to June 6th till July 5th, 2016. 25 patients with type 2 diabetes and stage 3 chronic kidney disease (CKD stage 3) were included in the study, who intended to fast during Ramadan. The aim was to observe the serum glucose level through 24 h FreeStyle Libre flash continuous glucose monitor (FSL-CGM). Most patients had three sensors during the study, covering an average three weeks during Ramadan and three weeks outside Ramadan (Sha'ban and shawal). We also monitored the change in, BP, HBA1c, kidney functions and BMI before and after Ramadan.

*Results:* This study included 25 adults with a mean age of 60 (±14 years). Fasting Ramadan did not result in any significant change in biophysical and biochemical profile of these patients. Data from FSL-CGM showed significantly longer duration (101.9 ± 119.1 Vs. 45.9 ± 47.6 min, $p < 0.033$) and more frequent hypoglycemic episodes (4.4 ± 4.7 Vs. 2.3 ± 3.0, $p < 0.047$) during Ramadan compared tonon-Ramadan respectively. The mean blood glucose readings were also significantly lower (70.7 ± 29.3 Vs.93.7 ± 57.9 mg/dl $p < 0.011$) during

*Abbreviations:* DM, Diabetes Mellitus; CKD-3, Chronic kidney Stage disease stage-3; T1DM, Type 1 Diabetes; T2DM, Type 2 Diabetes; HbA1c, Glycated hemoglobin; FSL-CGMS, FreeStyle Libre flash-Continuous Glucose Monitoring System; SMBG, Self-Monitoring of Blood Glucose; CSII, Continuous Subcutaneous Insulin Infusion; ADA, American Diabetic Association; IDF, International Diabetes Federation; DaR, Diabetes and Ramadan international Alliance; SU, SulphonylUrea; GLP-1 RA, glucagon-like peptide-1 receptor agonist; SGLT 2 I, Sodium Glucose Co Transport Inhibitor; DPP4I, Dipeptidyl Transferase 4 Inhibitors; UAE, United Arab Emirates; HDL, High Density Lipoprotein; LDL, Low Density Lipoprotein; BP, Blood Pressure; HE, Hypoglycemic Events

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Ramadan compared to non -fasting period. The renal function mean ± SD (serum creatinine 1.48 ± 0.37, 1.44 ± 0.37 and eGFR, 49.0 ± 18.4, 48.9 ± 17.5 p 0.9) showed no significant change due to fasting.

*Conclusion:* In patients with diabetes and CKD-stage 3 Ramadan fasting under close supervision and optimal diabetes care, was not associated with worsening of HBA1c and renal function. Patients had significantly more frequent and prolonged hypoglycemic episodes during Ramadan.



## 1. Introduction

Global prevalence of chronic kidney disease (CKD) in patients with diabetes is rising over the last two decades. Wild et al. estimated this increment from 2.8% to 4.4% of total diabetes population by the year 2030 [1].

Even in normal circumstances management of diabetes in patients with chronic kidney disease is considered significantly different from the patients without CKD. This discrimination is due to higher risk of hypoglycemia in these subjects following multiple pathophysiological changes. The half-lives of antidiabetic agents become prolonged due to decreased renal clearance of these drugs [2]. Patients usually suffer along with anorexia due to chronic uremic state and impaired gluconeogenesis secondary to reduced functional renal mass [3]. All these factors cumulatively contribute to higher risk of hypoglycemia and demand for a careful selection of pharmacological agents for them to avoid this risk [4].

Unfortunately, diabetes and its complications are more endemic in the developing and Arab countries; the areas where the Muslims are in the majority [5].

As per the IDF-DAR risk stratification patients with renal impairment are categorized under high risk of fasting Ramadan and they are advised against fasting [6]. This risk stratification is due to the relative increased risk of hypoglycemia and the possible worsening of renal functions due to prolonged dehydration. Therefore, fasting Ramadan is an important religious/health issue for both treating physician and patients. Patients under category of very high and high risk are advised against fasting. This classification and medical advice received a thorough review and agreement from Mufti of Egypt [7]. However, in a real-world setting, many patients usually prefer to fast despite advice against it [8]. Nevertheless it is also seen that Ramadan focused education play a significant role in reducing the frequency of hospitalization due to DKA and hypoglycemia [9,10].

There is lack of data that objectively assessed the real risk of hypoglycemia due to fasting Ramadan in these individuals. However many studies evaluated the impact of fasting on the kidney function at different stages of renal jeopardy with very variable results [11–13].

To understand the risk of hypoglycaemia during Ramadan fasting as well as the renal and other metabolic changes after Ramadan in patients with diabetes and chronic kidney disease stage 3 (CKD-Stage-3). We aimed to conduct this prospective study in a tertiary care hospital in Dubai during Ramadan 2016 that last from June 6th till July 5th through the use of 24 h FreeStyle Libre flash continuous glucose monitor (FSL-CGM). The use of this glucose monitoring system allowed recognition of the fluctuation of glucose level and timely intervention by patients to break their fast in case of hypo or hyperglycaemia. It helped them to avoid adverse effects and in safer fasting [14].

To the best of our research and knowledge, there is no study available till date that used continuous glucose monitoring in patients with diabetes and renal impairment aiming for objective stratification of hypoglycemia risk in this group of patients.

## 2. Methodology

### 2.1. *Ethical approval and funding*

The study was funded by a grant from Al-Jalila Foundation, Dubai, UAE of Dubai after competing for research grants by the foundation grant no AJF 201520. Ethical approval was obtained from Ethics and Research Committee of Dubai health authority. Informed consent was obtained from all the patients who participated in the study.

### 2.2. *Aim of the study*

#### 2.2.1. *Primary objectives*

To understand the glycemic changes through flash glucose monitoring data during Ramadan fasting in high-risk group of the patients with diabetes and CKD stage-3 and compare it with non-Ramadan. Glycemic changes including hypoglycemia (glucose level <70 mg/dl with or without symptoms), hyperglycemia (glucose level more than 250 mg/dl), the pattern of hypoglycemia over 24 h, and severity of hypoglycemia.

#### 2.2.2. *Secondary objectives*

- To Evaluate the safety of fasting Ramadan for patients with type 2 diabetes and chronic kidney disease stage 3 (CKD-3) through assessment of their renal parameters along with cardiovascular risk factors including BP, weight, BMI, lipids, Breaking fast when hypoglycemic or not.
- Number of days fasted.
- To record admission to hospital with complications of diabetes or worsening of underlying renal disease.

### 2.3. Study subjects

Patient attending diabetes and nephrology clinic of Dubai hospital, aged between 18 and 75 years with type 2 diabetes (T2DM) and stable CKD stage-3 (estimated glomerular filtration rate 30–60 ml/min), as calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula [15] were screened. Those who insisted on fasting despite advice against were invited to join the study. Recruitment started 1–2 months before Ramadan 2016. Patients with any recent hospitalisation or with known cardiovascular disease or pregnancy or hypoglycemia unawareness were excluded.

### 2.4. Method

Those who decided to fast were gathered for a 60 min pre-Ramadan focused education (DAR SAFA program that included information on safe fasting, when to break the fast during Ramadan, education on SMBG and use of glucometer and advice on dose adjustment for anti-diabetic medications, as well as dietary advise during Ramadan) [16]. All the patients were instructed about the importance of adequate hydration in non-fasting hours. Following the session, patients were asked to sign a consent form. We also took detailed treatment record as well as a history of hospital admission during the previous 3 months before study start.

Before commencing the educational session, all patients answered a simple questionnaire to assess their knowledge of safe fasting during Ramadan and their usual behavior during previous Ramadan. At the end of the session, they answered two questions to assess their benefit from the educational session. Post Ramadan, they also answered a questionnaire to assess their behavior during the corresponding Ramadan. All patients had training on FreeStyle Libre flash continuous glucose monitor (FSL-CGM) insertion and understanding its functions. This glucose monitoring system works through a sensor, which is inserted under the skin of upper arm through an applicator, and it stays in place via an adhering tape. The sensor monitored the interstitial glucose level every minute for two weeks. After two weeks, it is required to reinsert another sensor. This subcutaneous sensor needed to be scanned by a separate reader to keep a record of glucose measurement and pattern of glucose at the time of scan and up to 8 h before it. All subjects were instructed to check capillary blood glucose on symptoms of hypoglycemia or hyperglycemia. As this was a newer technology, so they were also advised if flash glucose sensor showed reading less than 60 mg% or more than 250 mg% to counter check the reading by capillary blood glucose [17]. All the patients were given out patient appointment to see the physicians during Ramadan for their medicine dose adjustment, they were also phone called to review their condition. During the visit for change of sensor, Diabetic educators downloaded data from the sensor on patients' visit, and the doctors suggested the modification in the doses of their medicines according to their glucose profile. Patients were provided with questionnaires on their visit to fill about their experience of fasting and use of the libre flash sensor. All of these measures are termed as optimal diabetic care during Ramadan.

All patients had their biophysical and biochemical profile recorded 2–4 weeks before and after Ramadan. That include the change in weight, Body mass index, systolic and diastolic blood pressure, HBA1c, lipids profile, renal functions (Fig. 1). We recorded the frequency and pattern of hypoglycemia during Ramadan fasting and non-fasting period. We also recorded the detail of medications, change in medication dose along with time and frequency of hypoglycemia. Any third-party assistance for hypoglycemia or hospitalisation was also recorded.

## 3. Data collection and analysis

All data were then entered into an excel sheet and was prepared for analysis. Paired Student's t-tests were used to test the significance of differences between values for continuous variables measured at baseline and at various time points. Independent t-test, one-way analysis of variance (ANOVA) and Chi-square (x2) test were used to assess the significance of differences between the groups. Continuous data are presented as the mean ± standard deviation (SD), and categorical data are presented as frequencies and percentages. Differences with P-values $\leq 0.05$ were considered to be statistically significant. Analyses were performed using Statistical Package for the Social Sciences (SPSS) version 23 (IBM Corp, New York, USA).

## 4. Results

Total of 25 patients was recruited. Out of which, one patient could not fast in Ramadan due to ill-health feeling. Another five patients dropped out from the study, after initial education session and consent. Three of them found it difficult to attend hospital during Ramadan, and two patients did not complete the study protocol. 19 patients completed the study, 11 were males, and 8 were females with the mean age of 60.5 years (±8.8) many patients were on different types of insulin regimens with or without oral hypoglycemic agents (Fig. 2).

### 4.1. Patients' behavior during fasting Ramadan

63% (n = 12) of patients' fast Ramadan 25–30 days and 32% (n = 6) of patients fast for more than 15 days and average days of fasting were 27. Despite the more frequent and prolonged hypoglycemic events during Ramadan in this group of the patient, only 42% (n = 8) patients experienced symptomatic hypoglycemia; however, only 4 broke their fast.

### 4.2. Glycemic changes and data from FSL-CGMS

Most patients had three sensors (FSL-CGM) during the study, covering an average three weeks during Ramadan and three weeks outside Ramadan (Sha'ban and shawal). A target for glycemic control was set between 70 and 130 mg/dl, the values are recorded as above or below the targets, and the comparison was made between Ramadan and non -Ramadan period (Table 1).

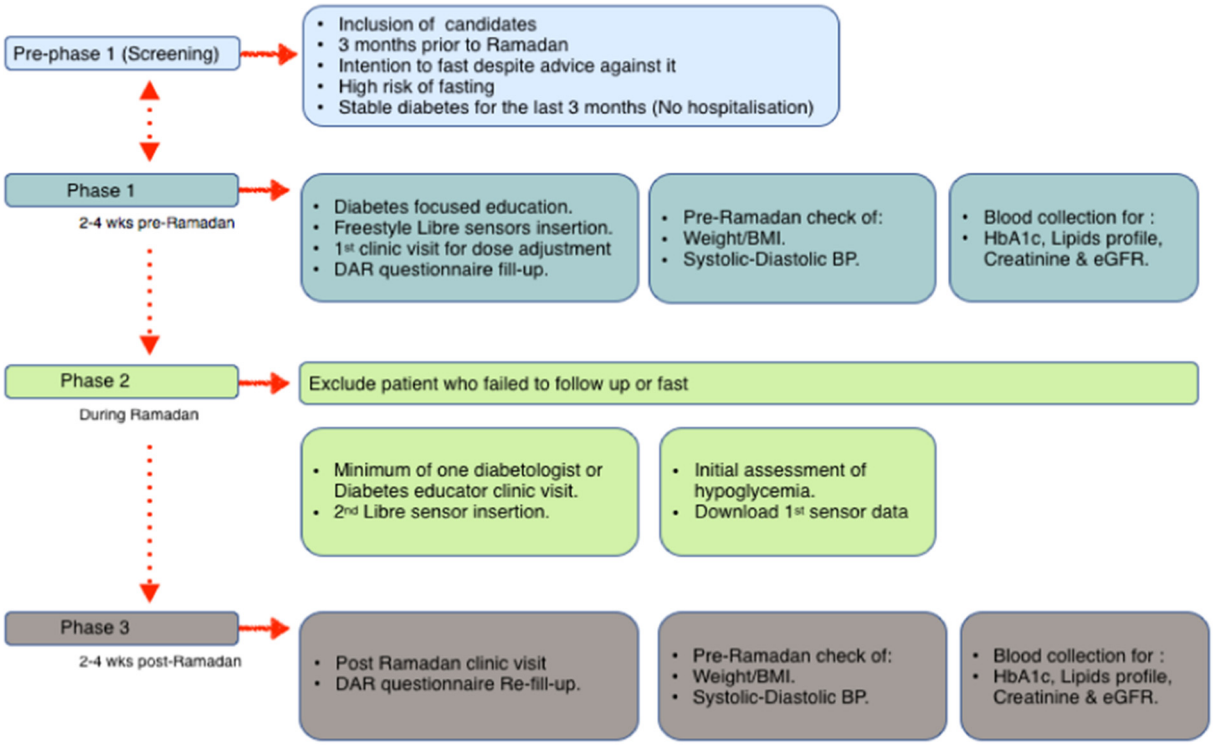


**Fig. 1 – Flow chart for study protocol.**

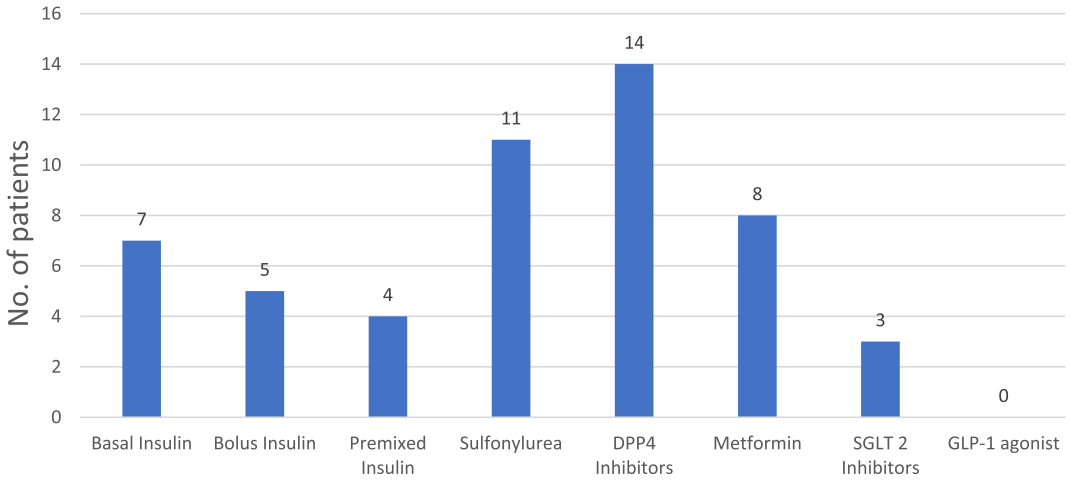


**Fig. 2 – The antidiabetic regimen of participants.**

There are hundred thousand glucose readings were available from FSL-CGM during fasting and non -fasting period and the results showed as mean SD. The captured data from the sensors showed a significant number of hypoglycemic events ($p < 0.047$) during Ramadan ($4.4 \pm 4.7$) compared to non -Ramadan period ($2.3 \pm 3.0$). With the lowest recorder mean glucose value during Ramadan $70.7 \pm 29.3$ mg/dl compared to outside Ramadan, $93.7 \pm 57.9$ mg/dl ($p < 0.011$). Results also showed that not only numbers and intensity of hypoglycemic events but also the duration of the hypoglycemia was also significantly increased during Ramadan $101.9 \pm 119.1$ min compared to non-Ramadan period $45.9 \pm 47.6$ min, $p < 0.033$ (Table 1).

The FSL-CGM data reflected the significant difference in the peak glucose value between Ramadan and outside Ramadan (333.3 mg/dl ± 98.2 and 295 mg/dl ± 80.7, $p < 0.039$). This wide fluctuation in glycemic profile is explained by consumption of more sweetened drinks and food due to hypoglycemic episodes before breaking fast.

The individual comparison of the difference in the hypoglycemic episodes between fasting and non-fasting states showed that 58% of the study subjects had more frequent

**Table 1 – Comparison of mean glucose values from FSL-CGM data. (Set target range in the FSL-CGM = 70–130 mg/dl.)**

| Parameter | Non-Ramadan (mean ± SD) | Ramadan (mean ± SD) | P Value |
|---|---|---|---|
| Average glucose (mg/dl) | 177.7 ± 71.8 | 176.9 ± 56.4 | 0.983 |
| Percentage above target | 65.0 ± 24.4 | 66.6 ± 26.2 | 0.653 |
| Percentage in target | 32.7 ± 23.6 | 30.6 ± 24.0 | 0.477 |
| Percentage below target | 2.3 ± 3.4 | 2.8 ± 3.8 | 0.551 |
| Peak glucose (mg/dl) | 295.8 ± 80.7 | 333.3 ± 98.2 | **0.039** |
| No. of hypo events | 2.3 ± 3.0 | 4.4 ± 4.7 | **0.047** |
| Average duration of hypoglycemia (min) | 45.9 ± 47.6 | 101.9 ± 119.1 | **0.033** |
| Lowest BG value (mg/dl) | 93.7 ± 57.9 | 70.7 ± 29.3 | **0.011** |
| No. of hypos 00:00–06:00 | 0.7 ± 1.2 | 1.4 ± 1.7 | 0.227 |
| No. of hypos 06:00–12:00 | 0.4 ± 1.0 | 0.4 ± 0.9 | 0.914 |
| No. of hypos 12:00–18:00 | 0.6 ± 1.1 | 2.0 ± 2.6 | 0.061 |
| No. of hypos 18:00–00:00 | 0.6 ± 1.5 | 0.6 ± 1.0 | 0.722 |

hypoglycemia during fasting Ramadan compared to outside Ramadan. Fifteen percent of patients had more than ten episodes of hypoglycemia during Ramadan fasting.

The patterns of hypoglycemic events also significantly differ during Ramadan, and hypoglycemic events were recorded at 1200–1800 h during Ramadan, compared to outside Ramadan (2.0 ± 2.6 vs 0.6 ± 1.1, p 0.061) (Fig. 3). The glucose level below 70 mg/dl in CGMS was seen in 50% of patients who developed hypoglycemia in Ramadan and 45% during non–Ramadan period. The mean HbA1c ± SD showed non-significant improvement 8 ± 1.1 non-Ramadan while during Ramadan it became 7.6 ± 1.4, p 0.983 (Table 2).

### 4.3. *Renal outcome and safety data*

No significant difference was observed in renal functions including serum urea, creatinine, e-GFR, and electrolytes before and after Ramadan fasting. The mean serum creatinine ± SD was 1.44 ± 0.37 in non-Ramadan period and 1.48 ± 0.37 during Ramadan fasting, p = 0.594. The eGFR was 48.9 ± 17.5 and 49.0 ± 18.4, p = 0.918 respectively. The cardiovascular risk factor measured as weight, blood pressure, and lipid parameters also did not show any significant change before and after Ramadan fasting (Table 2).

### 4.4. *Hospitalisation data*

None of the patients reported severe hypoglycemia, emergency room visit or hospitalisation due to any cause during and one month after the study period.

## 5. Discussion

Our study result showed almost doubling the rate and duration of hypoglycemia in the patients with diabetes and CKD-3, who observed fast during Ramadan compared to non-fasting period. As per the downloaded data from FSL-CGM and questionnaires' forms, none of these patients experienced severe hypoglycemia or hospitalisation due to any cause. The HbA1c and renal function did not show any deterioration at the end of the study. We could not find any research in the literature that monitor the risk of hypoglycemia and glycemic control as a primary outcome during Ramadan fasting in patients with diabetes and concurrent

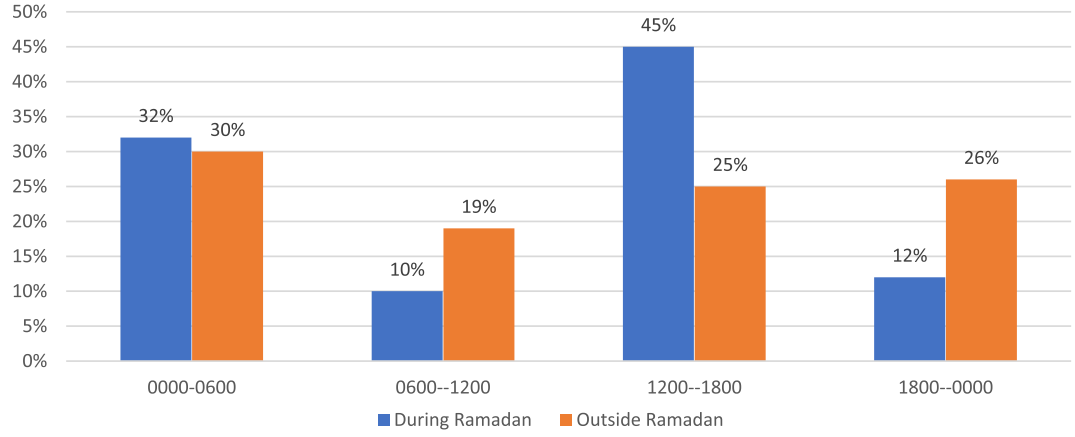


**Fig. 3 – Comparison of timings of hypoglycemia during and outside Ramadan.**

**Table 2 – Comparison of clinical and biochemical parameters.**

| Parameter | Non-Ramadan (mean ± SD) | Ramadan (mean ± SD) | P Value |
|---|---|---|---|
| Weight (kg) | 92.8 ± 24.2 | 92.6 ± 23.1 | 0.628 |
| Systolic BP (mmHg) | 140.5 ± 14.7 | 135.6 ± 19.6 | 0.193 |
| Diastolic BP (mmHg) | 72.2 ± 8 | 70.2 ± 12.4 | 0.320 |
| HBA1c (%) | 8 ± 1.1 | 7.6 ± 1.4 | 0.983 |
| Serum Creatinine (mg/dl) | 1.44 ± 0.37 | 1.48 ± 0.37 | 0.504 |
| e-GFR ((ml/min/1.73 $m^2$) | 48.9 ± 17.5 | 49.0 ± 18.4 | 0.918 |
| Urine ACR (mg/g Creatinine) | 487.7 ± 829.1 | 1152.3 ± 1954.4 | 0.208 |
| Serum Urea (mg/dl) | 47 ± 12.6 | 54 ± 19.3 | 0.552 |
| Uric Acid (mg/dl) | 7.3 ± 1.2 | 7 ± 1.3 | 0.531 |
| Serum LDL (mg/dl) | 76.7 ± 37.5 | 75.9 ± 34.4 | 0.705 |
| Serum cholesterol (mg/dl) | 160.2 ± 45.4 | 170.9 ± 73.1 | 0.327 |
| Serum Triglyceride (mg/dl) | 183.2 ± 95.6 | 218.7 ± 173.5 | 0.327 |

chronic kidney disease. However multiple studies are done that primarily addressed the renal outcome in this particular population. During the review of all these studies, only a few of them have reported the proportion of patients with diabetes and their glycemic changes in their results. Unlike to our research, one study in UAE by Bernie et al., 2010, done in 31 patients with CKD stage 2–5. Their cohort of patients with diabetes comprised of 61% patients (n = 19) who received Diabetes education before Ramadan. The results showed improved BP, eGFR, and the weight loss of 1.4 kg. The pre-Ramadan HBA1c was 6.8%, during Ramadan was 6.7%, and post-Ramadan was 7.4%. They also observed significantly higher blood glucose values (p 0.05) during Ramadan with a mean of 13.4 mmol/l, compared to pre-Ramadan (8 mmol/l) and post-Ramadan (11.2 mmol/l). There is no record of the incidence of hypoglycemia in this study [18].

Similar to our study Post Ramadan improvement in HBA1c was reported by a recent study from Saudi Arabia in their fraction of patients with Diabetes and CKD [19]. They collected data 3 months before, ten days after Ramadan and again three months after Ramadan from 65 patients with CKD 3 and above. Patients with diabetes comprised of 38.5% (n = 13) of their cohort. The mean HBA1c change was 8.2 ± 1.7, 8.2 ± 1.9 and 7.3 ± 1.1 pre, during and post Ramadan respectively with p 0.01. This study also showed significant improvement in BP during fasting Ramadan, but unlike to our study finding, out of all 69 patients, 22 subjects showed worsening of renal functions, 15 during the period of Ramadan and seven patients after Ramadan. The investigators did not report about incidence of hypoglycemia during the period of observation.

Some investigators documented no significant change in glycemic control in their fraction of patients with diabetes over the study period [20]. A prospective observational study from Malaysia by Wan Ahmad and colleagues (2011) on 35 patients with chronic hemodialysis. They aimed to monitor the safety of fasting in patients with diabetes (n = 17) versus those without diabetes (n = 18). They collected data including HBA1c, Fructosamine, renal functions, lipids and bone profile, BP, weight and hypotensive episodes, in the week before the beginning of Ramadan and the last week of Ramadan. In non -diabetics patients, the pre -Ramadan Fructosamine and HBA1c was 260 ± 116 and 5.6%±0.6 while post-Ramadan it became 289 ± 80 and 5.7% ±0.6. Diabetic patients showed fructosamine and HBA1c 356 ± 107 and 8.9%± 1.8, respectively. While post-Ramadan the Fructosamine and HBA1c were 361 ± 95 and 8.9%±1.8 respectively. They also recorded the number of self-reported hypoglycemia in study participants and similar to our findings their result also showed the increase in hypoglycemic episodes in diabetic patients during Ramadan fasting (9 events) compared to pre-Ramadan (5 episodes) [20,21].

Our results showed that most of the patients were able to tolerate Ramadan fasting with no adverse renal outcome like many other previous studies done in patients with different stages of CKD [22–24]. However, one investigator from Egypt showed the variable degree of reversible worsening in renal biochemical profile after Ramadan fasting. That trend was observed in those patients who already have an underlying Cardiovascular disease and was taking RAS blocker or diuretics for hypertension control [21].

In our study patients noticed hypoglycemia or hyperglycemia on CGM scanning, but they did not countercheck the reading by capillary prick and nor they broke their fast despite instructions for that. They relied more on their symptoms, and they tend to modify the doses for their antihyperglycemic agents subsequently. So we cannot align those abnormal observed readings in FSL-CGM with any reference capillary value. However, considered no severe hypoglycemia or hospitalisation is documented with the stable biochemical profile, self -monitoring by these modern modalities probably had helped for relatively safer fasting in these high-risk patients.

## 6. Conclusion

This study is unique by providing FSL-CGMS with high-quality medical care in such a high-risk group of patients. Patients with DM and moderate renal impairment experienced prolonged and more frequent hypoglycemia during Ramadan compared to non-Ramadan period. However, no severe hypoglycemia or hospitalisation was recorded. There is no deterioration seen in e-GFR, urea, and electrolytes in these patients after Ramadan fasting.

To anchor these findings, and to further confirm the risk stratification of diabetes patients and also to understand the

relationship of anti-diabetic agents with hypoglycemic events during Ramadan; larger multicenter studies are necessary.

## The significance of this study

Our study is first ever study that used FSL-CGMS to understand the risk of fasting in the patients with renal impairment. The result of the study confirmed that these patients are at risk of hypoglycemia but it also emphasised that Ramadan focus diabetes education along with close observation and continuous supervision may help them for a safer fasting in these high-risk patients. Our data also left few questions to be answered that why some patients were more prone to more hypoglycemic episodes despite sharing the similar high-risk profile.

The study needs to replicate on a larger group of the patients to further validate these results.

## Limitation of the study

Our study was conducted in small numbers of the patients, who were equipped FSL-CGM enabling them to anticipate any untoward glycemic change. They also received very close monitoring and supervision throughout the study period. This factor limits the generalizability of its result in real world setting. We suggest to further study these high-risk CKD stage-3 patients with a similar control group with-out optimum care, to understand the difference fasting risk between standard care group versus optimal care.

## Authors' contribution

Fatheya Alawadi. Supervision of the study, Fauzia Rashid, Organization of the study data collection, Data analysis and manuscript writing, Alaaeldin Bashier: Proposal writing, Maryam Al Saeed: Organization of the study and patients' education, Azza Khalifa: Organization of the study and patients' education, Elamin Abdelgadir: data collection, Fawzi Eltayb: CGMS data interpretation and analysis, Sona Abuelkheir: CGMS data interpretation and analysis. Mohammed Abdellatif: Phone calls, Fatima Sayyah: Data collection, Suad Khalifa: CGMS installation and education, Mohamed Hassanein: Manuscript review and supervision of the study.

## Consent of publication

Does not apply.

## Ethics approval and consent to participate

Ethical approval was obtained from the Dubai Health Authority Ethics committee. Approval document is available upon request.

## Competing interest

The authors declare that they have no competing interests.

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