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Biometric and metabolic changes in patients with diabetes prior, during and after the holy month of Ramadan (ABCD Study)

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ABSTRACT

Physiological impact of the intermittent or prolonged fasting is known from various studies on healthy subjects. However, data on impact of fasting on biochemical and biometric parameters in people with diabetes is building up. Safety of Ramadan fasting has always been assessed after Ramadan. This study looked into the immediate effect of fasting during the fasting days compared to time before and after the fasting month. Methods: This is an observational study. We looked into people with biometric and biochemical records before Ramadan, and we followed them up during and after Ramadan prospectively. We were aiming for assessing the biochemical and biometric changes for people with diabetes during Ramadan in comparison to pre-and post Ramadan. As well as the differences between these measures according to type and treatment of diabetes in those who fasted as well as in those who did not fast during Ramadan. Results: Total of 342 patients were recruited to the study. All were patients with diabetes at a mild to moderate risk of complications if fasted. Majority were males 52.3% (n = 180), while females were 47.7% (n = 162). Most of the results showed a U shape between Pre-Ramadan, During Ramadan and Post-Ramadan periods. there was a modest but significant reduction in weight but regained after Ramadan. Conclusions: Our study suggests that for many people with diabetes fasting is not associated with an increased risk to their glycemic control, their weight and/or their blood pressure. Indeed, what is seen is marginal benefit or no change in all parameters. This stratifies the ongoing recommendation that allows patients with categorized as low risk to fast Ramadan or non-Ramadan days whenever desired.

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1. Background

Many aspects related to the physiological impact of the intermittent or prolonged fasting on healthy subjects are well documented from various studies [1–4]. Furthermore, a larger number of studies that assesses the impact of fasting on patients with Diabetes mellitus (DM) are published over the last decade. Majority of those studies observed the impact

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of the religious intermittent fasting of Ramadan and identified the risks associated with fasting Ramadan as hypoglycemia, hyperglycemia, dehydration, hospitalization and thrombosis [6]. Consequently, guidelines have risk-stratified fasting in patients with diabetes into low, high and very high risk to fast [5]. Indeed, studies identified the role Ramadan-focused diabetes as an important tool to increase the safety of fasting Ramadan [7–10]. In most of these studies, fasting Ramadan resulted in a favorable effect on weight, lipids profile, and psychological status in both healthy individuals as well as patients with diabetes [1–4,7–9].

However, these studies classically compared these parameters before and after Ramadan and consequently, the exact impact of fasting from dawn to dusk in people with diabetes during Ramadan is in need for better understanding. This study is unique in its methods and flow, since the assessment was done during the last quarter of the fasting months, compared to pre and post Ramadan statuses. This should provide information on the immediate impact of fasting in patients with Diabetes. The study was accomplished in the Dubai health authority, the main governmental health organization in the emirate of Dubai – UAE.

2. Methodology

This is an observational prospective study. It was conducted across the primary and secondary care centers in the Dubai health authority in the UAE. All patients with type 2 diabetes mellitus (T2DM) who attended their clinic in the last quarter of Ramadan were listed. Patients who had pre-Ramadan (up to 3 months before Ramadan) biometric (weight, height, body mass index, systolic and diastolic blood pressure) and biochemical (HbA1c, lipids profile, creatinine and eGFR) indices were invited to participate in the study.

Patients who accepted to participate in the study were asked to repeat the same study parameters within 3 months after Ramadan (Fig. 1). Moreover, the same set of study parameters (biometric and biochemical parameters) were examined in the fourth week of Ramadan, with that we had set of data before, within last week, and after the month of Ramadan.

Inclusion criteria were patients with type 2 diabetes mellitus (T2DM), aged between 18 and 80 years, on oral hypoglycemic agents (OHA) with or without insulin. Those who did not fit the earlier mentioned criteria were excluded from the study. All patients received standard diabetes management during Ramadan.

2.1. Aim

We aimed for assessing the biochemical and biometric changes in people with diabetes during Ramadan (fourth week) in comparison to the pre-Ramadan (within 3 months) and post Ramadan (within 3 months) parameters. Last week of Ramadan was chosen to try to more accurately assess the impact of the first three weeks of fasting on the biometric and biochemical indices.

2.2. Ethics approval

The study was approved by the Dubai Health Authority ethics committee with a reference DSREC-06/2017_04.

2.3. Results

A total of 342 participant completed the study. All were patients with diabetes at a mild to moderate risk of complications if fasted. Majority were males 52.3% (n = 180), while females were 47.7% (n = 162). Mean age was 54 years.

Comparing the pre-Ramadan baseline and the last week of Ramadan, there was a modest but significant reduction in weight from 80.6 to 79.0 kg (p 0.003). There was a significant reduction in both systolic and diastolic blood pressures from 130 to 128 and from 76 to 75 mmHg with p value of 0.001 and 0.00 for systolic and diastolic blood pressures, respectively. Similarly, the mean HbA1c improved from 6.9 to 6.8% (p 0.002).

The serum creatinine showed a numerical stability but the different interquartile range 0.7 (0.0–0.8) to 0.7 (0.6–0.9) P 0.00 from pre-Ramadan to last week of Ramadan, respectively. However, the estimated glomerular filtration rate was

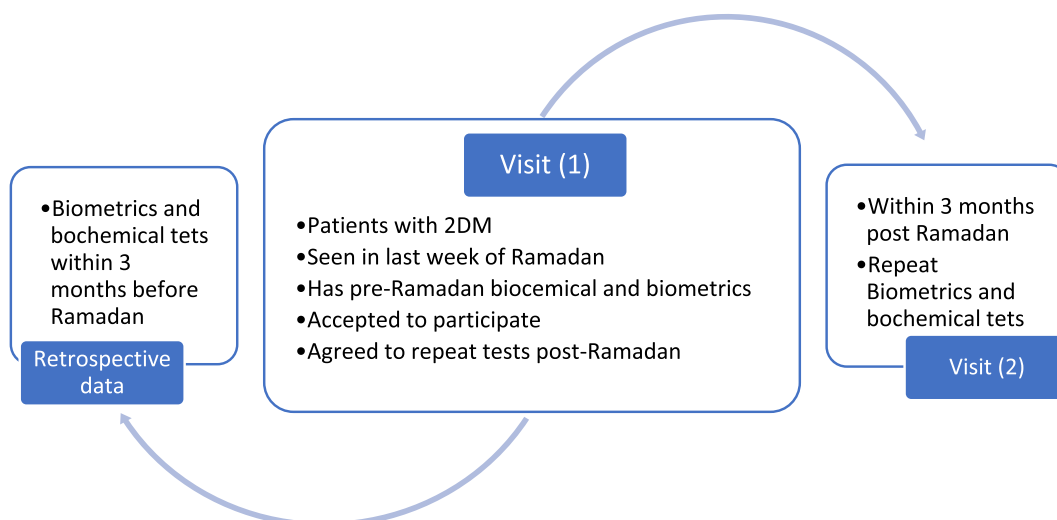


Fig. 1 – This graph describes the patient's study journey.

reduced from 102.6 pre-Ramadan to 99.75 in the last week of Ramadan (p 0.00).

All lipids panel rose at the end of Ramadan except the HDL which dropped with fasting (Table 1). The mean of change in all parameters was in favor of fasting benefits except for the lipids panel and the eGFR (Fig. 2). However, the mean serum creatinine remained within same mean levels (Fig. 2).

In order to assess the persistence of the changes in Ramadan, all parameters were repeated within 3 months after Ramadan. Weight returned to baseline, as well as HbA1c, creatinine, and HDL. Lipid panel improved after Ramadan, however, it did not return to baseline readings.

3. Discussion

The design of this study is unique compared to many other Ramadan studies in people with diabetes as this is the only study we are aware of that looked into biochemical and biometric markers during the last week of Ramadan and compared them to that of pre and post-Ramadan. Indeed, all other similar Ramadan studies in diabetics compared these parameters 1–3 months pre-Ramadan vs 1–3 months post Ramadan or they were retrospective in nature [10–12]. Conse-

quently, valuable information about changes during Ramadan were not accurately captured. Our cohort of patients were mostly from primary care settings and hence the use of insulin was minimal and mean baseline renal function was normal.

While Ramadan is a month of fasting, in many countries including the Gulf region, fasting during the day is usually followed by a large meal rich in carbohydrate and protein as well as frequent consumption of deserts. Indeed, Ramadan is known as the month of generosity and socializing which usually leads to excessive intake of food and drinks during the evening/night. In CREED and in DAR-MENA T2D studies, a sizeable proportion reported change in eating habits during Ramadan which included for many a higher intake of carbohydrate, fat and protein [13,14]. Hence, it is presumed that many people with DM gain weight during Ramadan and could end up with hyperglycemia. However, improvements in HbA1c was seen in DAR-MENA T2DM (HbA1c 8.0% pre to 7.5% post Ramadan) as well as CREED study (7.6% pre and 7.5% post Ramadan). In ABCD study glycaemia control as well as weight improved clinically and statistically during the last week of Ramadan. These improvements, were neutralized post Ramadan as both weight and HbA1c post-Ramadan were

Table 1 – This table shows the biometric and biochemical changes before, during the last week and after Ramadan.

Variables	Median (IQR)* Before Ramadan	Median (IQR)* During Ramadan	Before/During P Value	Median (IQR)* After Ramadan	During/After P Value
Weight (Kg)	80.6 [70.0–90.0]	79.0 [68.5–89.1]	0.003	80.0 [69.68–90.53]	0.003
BMI (Kg/m ²)	30.0 [26.72–34]	29.6 [26.4–33.92]	0.001	30.1 [26.7–34.18]	0.001
Systolic BP (mmHg)	130.0 [120.0–140.0]	128.0 [116.0–139.0]	0.00	128.0 [120.0–138.0]	0.088
Diastolic BP (mmHg)	76.0 [69.0–84.0]	75.0 [67.0–83.0]	0.001	75.0 [67.0–82.0]	0.86
HbA1c (%)	6.9 [6.3–7.93]	6.8 [6.2–7.6]	0.002	6.9 [6.2–7.8]	0.35
Total Cholesterol (mg/dl)	156.0 [133.5–184.0]	158.0 [134.0–182.0]	0.08	154.0 [129.0–176.5]	0.04
Triglycerides (mg/dl)	120.0 [91.0–165.5]	122.5 [87.0–162.75]	0.27	121.0 [91.5–160.0]	0.68
HDL (mg/dl)	47.0 [40.0–56.0]	46.0 [39.0–54.0]	0.00	45.0 [38.0–54.0]	0.16
LDL (mg/dl)	84.0 [64.0–113.0]	90.0 [68.0–116.0]	0.068	86.0 [64.0–105.0]	0.07
Creatinine (mg/dl)	0.7 [0.5–0.8]	0.7 [0.6–0.9]	0.00	0.7 [0.6–0.8]	0.002
Estimated GFR (ml/min/m ²)	102.6 [93.1–112.5]	99.75 [88.48–109.4]	0.00	101.2 [91.8–110.8]	0.005

* IQR: Interquartile Range.

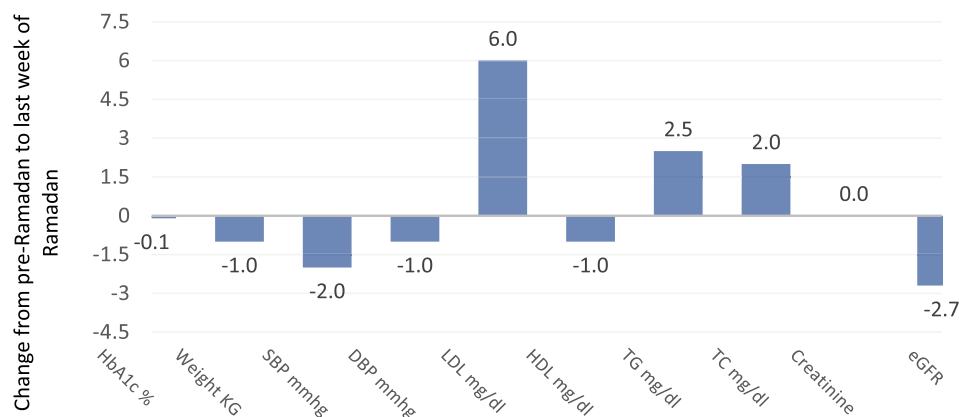


Fig. 2 – This graph describes the mean change for different metabolic parameters between the baseline pre-Ramadan state and the last week of Ramadan.

Table 2 – This table shows the mean change in different metabolic parameters at different peri-Ramadan periods.

	ABCD-Ramadan		DAR-MENA T2D		Optimum Care-Dubai	
	Change	P value	Change	P value	Change	P value
HbA1c %	−0.1	0.002	−0.5	<0.0001	−0.3%	0.000
Weight KG	−1.0	0.000	−0.6	<0.0001	0.1	0.315
SBP mmhg	−2	0.000	−3.1	<0.0001	0.1	0.336
DBP mmhg	−1	0.001	−0.3	0.525	−0.09	0.181
LDL mg/dl	6	0.06	−5.2	<0.0001	4.9	0.037
HDL mg/dl	−1	0.000	1.0	0.059	0.6	0.239
TG mg/dl	2.5	0.689	−2.6	0.306	13.8	0.065
TC mg/dl	2	0.045	−4.9	0.001	6.5	0.072
Creatinine	0	0.000	NA	–	0.01	0.311
eGFR	−2.7	0.000	NA	–	−0.07	0.084

more or less equivalent to pre-Ramadan. These minor changes occurred despite the usual eating and social habits that prevail in Ramadan in recent decades in the Gulf region. The classical teaching in Islam, is to try not to fill the stomach with food beyond a third of its capacity. One, wonders, what would be the outcome if this teaching is applied for people with diabetes during Ramadan and beyond.

The biochemical and biometric changes seen in ABCD study are all compared to those reported in DAR-MENA T2D or Optimum care -Dubai study (Table 2). Contrary to the low risk fasting group seen in ABCD study, Optimum care-Dubai study, which was conducted in Dubai hospital, looked into a higher risk of fasting such as people with type 1 diabetes, type 2 diabetes treated with insulin, type 2 diabetes with CKD stage 3 or stable IHD or gestational diabetics [15]. Similar to ABCD study, they all shared with ABCD study the same geographical and cultural habits during Ramadan. DAR MENA T2D was a large study from 10 different countries in MENA region. However, regardless of location or cultural habits it seems that many people with diabetes during Ramadan has similar biochemical and biometric changes.

It is important to remember that DAR-MENA and Optimum care studies looked into these parameters post Ramadan. For lipids and renal markers there's marginal increase that is either not statistically significant, or clinically not significant or both. From clinical aspects, there seems to be no obvious clinical harm. This is an important point as various guidelines in Ramadan for people with diabetes classify people as a minimum of low risk while we here we see a minimum of no harm or benefit [5].

4. Conclusions

Our study suggests that for many people with diabetes fasting is not associated with an increased risk to their glycemic control, their weight and/or their blood pressure. Indeed, what is seen is marginal benefit or no change in all parameters. This stratifies the ongoing recommendation that allows patients with categorised as low risk to fast Ramadan or non-Ramadan days whenever desired.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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