

# Follow-up and treatment pattern during Ramadan and evaluation of the outcome of Ramadan fasting on clinical, biochemical and metabolic parameters in patients with type 2 diabetes mellitus: a real-world, multi-center, prospective observational study

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## ABSTRACT

**Background:** There are variable effects of Ramadan fasting on clinical and biochemical variables of diabetic people. Anti-diabetic agents are often adjusted during this time to reflect changes in lifestyle. The study was conducted to understand the diversity of follow-up, treatment pattern, clinical, and biochemical outcome of Ramadan fasting among type 2 diabetic patients who observed Ramadan fast.

**Methods:** This real-world, multi-center, prospective, observational study was conducted at the diabetes outpatient department of National Healthcare Network (NHN) Uttara Center of Bangladesh Diabetic Society (BADAS), Dhaka, Bangladesh and outpatient department of MARKS Hormone and Diabetes clinic, MARKS Medical College & Hospital in Dhaka, Bangladesh upon randomly selected type 2 diabetic patients, recruited 1 to 12 weeks prior to the Ramadan and followed up till 12 weeks post-Ramadan period. Finally, a total of 271 participants completed satisfactory follow up. Data was collected before, during, and after Ramadan using a set of questionnaires in a face to face interview.

**Results:** The majority (80.1%) of participants received pre-Ramadan education, counseling, adjustment of medication and other direction to help them cope with Ramadan fasting. A significant reduction of weight, body mass index (BMI) and blood pressure were reported after Ramadan fast ( $p < 0.001$ ). None of the studied participants experienced severe hyper/hypoglycemia or acute complications requiring hospitalization or an emergency room visit. Metformin was the commonest prescribed anti-diabetic medication. Premixed insulin was the commonest insulin regimen during study period. Three most commonly adjusted oral anti-diabetic drugs were gliclazide, glimepiride, metformin and insulin doses were also adjusted. Mean of fasting and prandial capillary blood glucose decreased from pre-Ramadan period to post-Ramadan period ( $P < 0.05$ ). HbA1c decreased during post-Ramadan period compared to pre-Ramadan visit ( $P = 0.13$ ). A significant reduction in the triglyceride level was observed during post-Ramadan follow up ( $P < 0.05$ ).

**Conclusion:** The study revealed that a safe fasting can be observed with proper pre-Ramadan work-up. Ramadan fasting resulted into significant reduction of weight, BMI, blood pressure, lipid profile and improved glycemic status in patients with type 2 diabetes.

**Key words:** Ramadan outcome, diabetes treatment pattern, type 2 diabetes mellitus.

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## INTRODUCTION

It is obligatory on all healthy Muslim adults to fast during Ramadan. Sick people who can be adversely affected by fasting, are exempted from this according to the Holy Qur'an.<sup>1</sup> However, patients who are prone to develop hypoglycemia and hyperglycemia, many still insist on performing Ramadan fasting. It is estimated that 50 million people with diabetes fast each year<sup>2</sup> and majority of them lives in Asia-Pacific, Middle East, North Africa region and rest in Europe, North and South America.<sup>3</sup>

Fasting during Ramadan requires abstinence for eating, drinking and smoking from dawn to sunset. Length of the fast varies from 11 to 20 hours, depending on season and geographical locations. Moreover, changes in sleep pattern, eating habit, physical activities can potentially induce metabolic alterations in both healthy and diseased Muslims.<sup>4</sup> The overall calorie consumption of individuals with type 2 diabetes has been reported to increase during Ramadan.<sup>5</sup> Moreover, the doses of anti-diabetic agents are often adjusted during this time to reflect the changes in lifestyle.<sup>6</sup>

The Ramadan Education and Awareness in Diabetes study READ was a retrospective study that assessed safety of Ramadan fasting on Muslims with type 2 diabetes who attended a structured educational program that included education regarding physical activity, meal plan, glucose monitoring, hypoglycemia, dosing and timing of medication. The study revealed that total number of hypoglycemic events was significantly less among patients those had structured education in the pre-Ramadan period.<sup>7</sup> There are also variable evidences of effects of Ramadan fasting on biochemical variables of diabetic people.<sup>8</sup>

However, pragmatic prospective studies evaluating clinically relevant events in diabetic patients who fast are relatively scarce. Most of the studies are either small-scaled, recruiting even fewer than 60 subjects or retrospective.<sup>9,10,11,12</sup> This study was designed to fill this gap. The main objectives of this prospective study were:

- to understanding the diversity of follow-up and treatment pattern of patients with Type 2 Diabetes Mellitus (T2DM) during Ramadan;
- to evaluate the effects of Ramadan fasting on clinical, biochemical and metabolic parameters in T2DM patients;
- to determine the proportion of diabetic patients who develop hypo/hyperglycemic episodes, need

hospitalization or an emergency room visit due to adverse events while fasting during the month of Ramadan.

## METHODS

### Study design

This was a real-world, multi-center, prospective, observational study conducted at the Diabetes outpatient department of National Healthcare Network (NHN) Uttara Center of Bangladesh Diabetic Society (BADAS), Dhaka, Bangladesh and outpatient department of MARKS Hormone and Diabetes clinic, MARKS Medical College & Hospital in Dhaka, Bangladesh. Potential adult patients having T2DM were screened and approached to determine their interest in participating in this study before Ramadan. Upon consent, a pre-formed data record form was used to collect data in a face to face interview including investigation reports those done before, during, and after Ramadan.

### Study period

The study was carried out from January 2017 to December of 2017. Literature review and formulation of study design was done during January-February of 2017. Study sample enrollment started from March of 2017. Data were collected during March to October of same year. Data was processed and analyzed during November-December of 2017.

### Study sample

Initially 345 subjects were recruited. Finally, a total of 271 participants completed satisfactory follow up and were studied.

### Eligibility criteria

Patients over 25 years of age having type 2 diabetes mellitus for more than a year, who were willing to take part in the study, were included. The patients who were not willing to take part in the study, pregnant and lactating women, having T1DM, having current acute illness, those who received short term corticosteroid therapy were excluded from the study.

### Study tools and operational definitions

**a. Data record form:** The data record form used in this study encompassed a section on socio-demographic and clinical information of participants that included age, gender, level of

education, employment status, body mass index, duration of diabetes, complications and comorbidities. Another section included information on types of anti-diabetic agents used and dose regimens, adjustments made to the medication during Ramadan. Outcome measures, such as blood glucose profile, HbA1c, liver enzymes, s. creatinine, and lipid profile were collected before and after Ramadan. The studied participants were also asked about any event of hypoglycemia or hyperglycemia, dehydration and others complication or illness during Ramadan fasting and whether they had to visit an emergency room or required hospitalization due to adverse glycemic events during study period.

**b. Self-monitoring of blood glucose (SMBG):**

Following SMBG Protocol was provided with participants: to check capillary blood glucose pre-Suhoor, early morning 2 to 4 hours after Suhoor, mid-day between 11 am to 1pm, pre-Iftar, 2-hours after Iftar, at any time when there were symptoms of hypoglycemia / hyperglycemia or feeling unwell. Subjects with very high risk/high risk who fasted against medical advice, SMBG were advised for multiple times of day. Moderate and low risk patients were instructed to monitor their blood sugar, at the following times: pre-Suhoor, midday, pre-Iftar, 2-hour post-Iftar or whenever symptoms of hypoglycemia or acute illness occur.<sup>13</sup>

**c. Hypoglycemia:** It has been defined as plasma glucose value  $\leq 70$  mg/dL ( $\leq 3.9$  mmol/L) and severe hypoglycemia is defined as event of hypoglycemia characterized by altered mental and or physical status requiring assistance for recovery.<sup>14</sup>

**d. Hyperglycemia:** Hyperglycemia is the term for high blood glucose that happens when the body has too little insulin or when the body can't use insulin properly.<sup>15</sup>

**e. Diabetic Ketoacidosis (DKA):** A blood glucose  $>250$  mg/dl (13.9 mmol/L), moderate degree of ketonemia and/or ketonuria, an arterial pH  $<7.3$ , a serum bicarbonate ( $\text{HCO}_3^-$ )  $<15$  mEq/L and an increased anion gap metabolic acidosis define diagnosis of DKA.<sup>16</sup>

**f. Dehydration:** Mild to moderate dehydration was defined through dry mouth/tongue, thirst, headache, lethargy, fatigue, dry skin, muscle weakness, light-headedness, dizziness and a lack of focus. Severe dehydration was defined through sunken eyes, lack

of tears, hypotension, tachycardia and, in the worst-case scenario, unconsciousness.<sup>17, 18</sup>

**g. Instruction on when to break the fast:**

Participants were instructed to break the fast when blood glucose was  $<3.9$  mmol/L or  $\leq 16.7$  mmol/L, if they felt unwell, experienced symptoms of hypoglycemia and during acute illness.<sup>19</sup>

**Data record procedure**

Data of each participant was recorded at three visits. The first Pre-Ramadan visit was recorded from or before twelve weeks until one week prior to onset of Ramadan (visit-1), the second Ramadan visit was made during the month of Ramadan (visit-2), and the third Post-Ramadan visit was recorded starting from one week up to twelve weeks after end of Ramadan (visit-3). The data record form was completed by the trained interviewers.

During Pre-Ramadan visit (visit-1), the socio-demographic, clinical and biochemical profile of studied participants were recorded. Structured education on symptoms of hypoglycemia hyperglycemia, DKA, dehydration, other possible complications, SMBG protocol, when should break the fast, diet plan and exercise advice were delivered. Blood samples were collected for baseline investigations. The participants were requested to measure their capillary blood glucose levels using a glucometer. The values were charted by the patients and were later recorded during subsequent visit. The participants were also requested to report any hypo/hyperglycemic or other events e.g.; visit to emergency room or hospitalization. As per standard Ramadan recommendation, anti-diabetic medications were adjusted.

During Ramadan follow-up (visit-2), along with SMBG records, any event of hypoglycemia or hyperglycemia, dehydration and others complication or illness during Ramadan fasting and visit to emergency room or hospitalization due to adverse glycemic events were recorded.

During Post-Ramadan visit (visit-3), clinical and biochemical profiles of participants were reviewed and final outcome were measured.

**Statistical analysis**

Data were analyzed using IBM SPSS for Windows version 20.0 (IBM SPSS Statistics for Windows, Version 20.0 IBM Corp. Armonk, NY, USA). Frequencies and percentages were calculated for quantitative variables, while mean  $\pm$  SD were documented for qualitative variables. Categorical variables were compared with

each other using the chi-square test. Among the basic characteristics of the studied participants, the continuous variables were compared with each other using the ANOVA test. For parametric parameters both one sampled and paired *t* test was used to analyze the changes in clinical and biochemical parameters before and after Ramadan. Statistical significance was set at  $P < 0.05$ .

## RESULTS

### Studied participants characteristics

A total of 271 patients with Type 2 DM, age ranging from 27 to 84 years participated in this study which

included 128 men and 143 women with a sex ratio of 0.89. Mean of duration of diabetes of participants was  $6.28 \pm 10.15$  years (Table I). A large majority ( $n = 160$ ; 59.0%) of the studied subjects had at least up to 12th grade education and 45% of the participants were homemaker ( $n = 123$ ; 45.38 %, all of them were female). Majority ( $n = 143$ ; 86%) of the studied participants had co-morbidities and diabetes related chronic complications. Clinical parameter studied during pre-Ramadan and post-Ramadan period is mentioned in Table II. Few participants had history of hypoglycemia (1.1%) and keto-acidosis (3.7%) at least three months prior Ramadan (Table III).

**Table I** Socio-demographic parameter of studied subjects (N= 271)

Variables		Total (N =271)	Male (n =128)	Female (n =143)	p value
Age (yrs)(Mean $\pm$ SD)	43.31 $\pm$ 10.26	48.65 $\pm$ 10.60	46.10 $\pm$ 9.82	0.04	
Duration of DM (yrs) (Mean $\pm$ SD)	6.28 $\pm$ 10.15	5.85 $\pm$ 4.56	6.66 $\pm$ 13.31	0.51	
Education[N (%)]	< S.S.C	111 (41.0)	35 (27.34)	76 (53.14)	0.000
	>S.S.C	160 (59.0)	93 (72.65)	67 (46.85)	
Occupation[N (%)]	Service Holder	81 (29.9)	72 (56.25)	9 (6.29)	0.000
	Businessman	19 (7.01)	18 (14.06)	1 (0.69)	
	Retired	48 (17.71)	38 (26.68)	10 (86.01)	
	Homemaker	123 (45.38)	0 (0.0)	123 (45.38)	

SSC: Secondary School Certificate; ANOVA and Chi-square analysis were done.

**Table II** Clinical parameter differences during pre-Ramadan and post-Ramadan period (N=271)

Variables	Before Ramadan			After Ramadan			P value
	Mean $\pm$ SD	S.E. mean	<i>t</i> value	Mean $\pm$ SD	S.E. mean	<i>t</i> value	
Weight (kg)	64.71 $\pm$ 9.96	0.60	106.87	64.37 $\pm$ 9.72	0.59	108.94	0.000
BMI (kg/m <sup>2</sup> )	26.42 $\pm$ 4.91	0.29	88.44	26.29 $\pm$ 4.07	0.24	106.15	0.000
SBP (mm Hg)	126.77 $\pm$ 14.39	0.87	144.97	121.07 $\pm$ 9.27	0.57	208.89	0.000
DBP (mm Hg)	79.44 $\pm$ 7.38	0.44	177.14	78.35 $\pm$ 5.56	0.34	225.14	0.000

BMI: body mass Index; SBP: systolic Blood Pressure; DBP: diastolic Blood Pressure; One Samples *t* Test was done.

**Table III** Pre-Ramadan assessment of studied subjects (N =271)

Variables		Total (N =271)		Male(N =128)		Female(N =143)		p value
		n	%	n	%	n	%	
Pre-Ramadan	Present year	217	80.10	99	77.34	118	82.51	0.287
Counseling	Past year	54	19.90	29	22.65	25	17.48	
Hypoglycemia	No	268	98.0	126	98.43	142	99.30	0.498
	3 months prior Ramadan	3	1.1	2	1.56	1	0.69	
Keto-acidosis	No	261	96.3	123	96.09	138	96.50	0.335
	3 months prior Ramadan	10	3.7	5	2.34	5	3.49	

Chi-square analysis was done

**Diversity of peri-Ramadan follow-up**

The majority (80.1%) received pre-Ramadan education and counseling on medication adjustment, meal, exercise, when to break fasting rules, SMBG etc. However, all of them (100.0%) went for a medication review prior one to twelve weeks or more by their physician before they began fasting. Pattern of follow up during pre-Ramadan and post-Ramadan period is

mentioned in Table IV. Only 26.2% of participants did practice regular self-monitoring of blood glucose (SMBG) during Ramadan while rest (73.2%) did not (Table V). In this study, none of the studied participant experienced severe hypo/hyperglycemia requiring hospitalization or an emergency room visit. Few developed dehydration and fever during Ramadan fasting period (3.70% & 2.20% respectively) (Table V).

**Table IV** Follow up pattern during pre-Ramadan and post-Ramadan period (N=271)

Variables	Pre-Ramadan				Post-Ramadan				
	Total	Male	Female	p	Total	Male	Female	p	
	N (%)	n (%)	n (%)	value	N (%)	n (%)	n (%)	value	
Followup (week)	No	0 (0.0)	0 (0.0)	0 (0.0)	0.11	14(5.20)	8(6.25)	6 (4.19)	0.21
	< 1 Week	29(10.70)	20(15.62)	9(6.29)		10(3.70)	7(5.46)	3 (2.09)	
	1-2 Week	115(42.40)	48(37.50)	67(46.85)		58(21.40)	32(25.0)	26(18.18)	
	2-4 Week	95 (35.10)	43(33.59)	52(36.36)		148(54.60)	62(48.43)	86(60.13)	
	4-12 Week	26 (9.60)	14 (10.93)	12(8.39)		41 (15.10)	19(14.84)	22(15.38)	
>12 Week	6(2.20)	3(2.34)	3(2.09)		0 (0.0)	0 (0.0)	0 (0.0)		

Chi-square analysis was done.

**Table V** Pattern of follow-up, SMBG and complication during Ramadan among subjects (N=271)

Variables	Total (N =271)		Male (n =128)		Female (n =143)		P value	
	n	%	n	%	n	%		
Follow-up during Ramadan (Week)	No	12	4.40	9	7.03	3	2.09	0.27
	1 <sup>st</sup> Week	70	25.80	36	28.12	34	23.77	
	2 <sup>nd</sup> Week	167	61.60	73	57.03	94	65.73	
	3 <sup>rd</sup> Week	14	5.20	6	4.68	8	5.59	
	4 <sup>th</sup> Week	8	3.0	4	3.12	4	2.79	
SMBG (Week)	No	200	73.80	91	71.09	109	76.22	0.403
	1 <sup>st</sup> Week	29	10.70	13	10.15	16	11.18	
	2 <sup>nd</sup> Week	36	13.30	19	14.84	17	11.88	
	3 <sup>rd</sup> Week	5	1.80	4	3.12	1	0.69	
	4 <sup>th</sup> Week	1	0.4	1	0.78	0	0.0	
Complication During Ramadan	No Complication	265	97.80	124	96.87	141	98.60	0.335
	Dehydration	10	3.70	3	2.34	7	4.89	
	Fever	6	2.20	4	3.12	2	1.39	
Hospitalization/Emergency room visit due to severe Hypo/ hyperglycemia	0	0.0	0	0.0	0	0.0		

SMBG: Self Monitoring of Blood Glucose; Chi-square analysis was done.

### Treatment pattern during Ramadan

Metformin was the commonest prescribed anti-diabetic medication all through the pre [232(85.60%)] to post [234 (86.30%)] Ramadan follow-up; used alone or in combination with other oral anti-diabetic drugs (OADs) or insulin. A good number of participants were managed with sulfonylurea (most frequent are gliclazide and glimepiride) alone or in combination with other OADs or insulin during both pre [169(62.4%)] and post [166 (61.30%)] Ramadan follow-up. Premixed insulin was the commonest insulin regimen during study period. Prescribed Insulin regimen alone or with OADs were as following: premixed insulin [pre vs. Post Ramadan: 69 (25.50%) vs. 64 (23.60%)], basal insulin concurrently with mealtime insulin [pre vs. Post Ramadan: 34(12.50%) vs. 35(12.90%)].

### Dose adjustment pattern of anti-diabetic medications during Ramadan

This study showed that, the three most commonly adjusted OADs were metformin, gliclazide and glimepiride with mean dose of 1020.60±350.68 mg, 76.47± 27.05 mg and 2.25±9.65 mg respectively during Ramadan (all dose were reduced); and 1088.0±686.46 mg, 102.63 ± 40.47 mg and 3.97±19.50 mg respectively after Ramadan. Patients were treated with a stable dose of DPP4 inhibitors (sitagliptin and vildagliptin) throughout the studied period. The mean of dose (with reduction) of insulin for premixed and basal insulin were: 32.08± 9.22 units and 15.0±4.21 unit respectively during Ramadan period while 63.55± 88.58 units (increased dose) and 18.96±4.39 unit (increase) respectively after Ramadan period (Table VI&VII).

**Table VI** Mean daily dose of OADs and insulin before and during Ramadan

Treatment Modalities	Before Ramadan		During Ramadan		Paired <i>t</i> Test		sig (two-tailed)	
	Mean ± SD	S.E. mean	Mean ± SD	S.E. mean	<i>t</i> value	<i>df</i>		
OAD (daily dose in mg)	Gliclazide	101.18±40.47	4.00	76.47±27.05	2.67	7.71	101	0.000
	Glimepiride	3.95±19.36	2.36	2.25±9.65	1.17	1.43	66	0.157
	Metformin	1099.80±893.17	58.51	1020.60±350.68	22.97	1.50	232	0.135
	DPP4 in.	53.95±19.94	2.21	54.56±20.58	2.28	-1.00	80	0.320
Insulin (daily dose in Unit)	Premixed	42.17±12.23	1.47	32.08±9.22	1.11	11.08	68	0.000
	Basal	19.47±5.51	0.94	15.00±4.21	0.72	5.67	33	0.000
	Bolus	34.22±12.82	4.27	58.33±77.85	25.95	-0.973	8	0.359

OADs: Oral Anti-diabetic Drugs; DPP4in: Di-Peptidyl-peptidase 4 inhibitors; Paired Samples *t* Test was done

**Table VII** Mean daily dose of OADs and insulin before and after Ramadan

Treatment Modalities	Before Ramadan		After Ramadan		<i>t</i> value	<i>df</i>	sig (two-tailed)	
	Mean ± SD	S.E. mean	Mean ± SD	S.E. mean				
OAD(daily dose in mg)	Gliclazide	100.20±40.15	4.06	102.63±40.47	2.67	-1.179	98	0.241
	Glimepiride	3.96±19.51	2.40	3.97±19.50	2.40	-0.184	65	0.854
	Metformin	1093.30±898.78	59.39	1088.0±686.46	45.36	0.079	228	0.937
	DPP4 in.	53.50±19.75	2.25	54.15±20.44	2.33	-1.00	76	0.320
Insulin(daily dose in Unit)	Premixed	42.69±11.81	1.48	63.55±88.58	11.16	-1.894	62	0.063
	Basal	19.33±5.53	0.96	18.96±4.39	0.76	0.516	32	0.609
	Bolus	33.25±13.34	4.71	38.00±18.17	6.42	-1.245	7	0.253

OADs: Oral Anti-diabetic Drugs; DPP4in: Di-Peptidyl-Peptidase 4 inhibitors; Paired Samples *t* Test was done

**Table VIII** Differences of glycemc and other biochemical parameters before and after Ramadan of studied subjects

Biochemical and glycemc parameters	Mean $\pm$ SD	Before Ramadan		After Ramadan		Paired <i>t</i> Test		Sig (two-tailed)
		S.E. mean	Mean $\pm$ SD	S.E. mean		<i>t</i> value	<i>df</i>	
Blood glucose Profile	FBG	9.27 $\pm$ 4.31	0.29	8.46 $\pm$ 2.67	0.18	2.54	210	0.012
	2h ABF	12.58 $\pm$ 4.12	0.28	11.12 $\pm$ 3.37	0.23	5.35	209	0.000
	HbA1c	8.95 $\pm$ 1.95	0.48	8.09 $\pm$ 1.45	0.36	1.58	15	0.134
Liver Enzymes	ALT	51.10 $\pm$ 18.10	5.70	45.60 $\pm$ 11.70	3.70	0.94	9	0.368
Renal Function Test	S. Creatinine	0.98 $\pm$ 0.25	0.07	0.92 $\pm$ 0.20	0.06	1.21	10	0.251
Lipid Profiles	Total Cholesterol	199.50 $\pm$ 33.65	10.64	182.20 $\pm$ 29.32	9.27	1.97	9	0.08
	HDL	35.77 $\pm$ 4.76	1.58	39.88 $\pm$ 3.21	1.07	-2.09	8	0.069
	LDL	114.50 $\pm$ 26.46	7.63	100.42 $\pm$ 25.73	7.42	2.12	11	0.057
	TG	159.08 $\pm$ 56.85	16.41	101.33 $\pm$ 63.95	18.46	3.49	11	0.005

FBS: Fasting Blood Glucose (mmol/L); 2h ABF: 2-hour After Breakfast (mmol/L); ALT: Alanine Aminotransferase (U/L); HDL: High Density Lipoprotein (mg/dl); LDL: Low Density Lipoprotein (mg/dl); TG: Triglyceride (mg/dl); HbA1c in %. Paired Samples *t* Test was done.

### Outcome of Ramadan fasting on clinical parameters

As with BMI (kg/m<sup>2</sup>), significant reduction of body weight was recorded after Ramadan fasting in comparison to pre-Ramadan period ( $p < 0.001$ ). There was significant reduction of both systolic and diastolic blood pressure during post-Ramadan follow up ( $p < 0.001$ ) (Table II).

### Outcome of Ramadan fasting on biochemical parameters

Mean of fasting capillary blood glucose decreased significantly from pre-Ramadan period to post-Ramadan period (9.27 $\pm$ 4.31 mmol/L vs. 8.46 $\pm$  2.67 mmol/L;  $P < 0.05$ ) and prandial blood glucose showed similar trend ( $P < 0.05$ ). HbA1c decreased during post-Ramadan visit compared to pre-Ramadan visit (8.09% vs. 8.95% respectively;  $P = 0.13$ ). Mean of serum creatinine of studied participants varied slightly from pre-Ramadan to post-Ramadan visit (0.98 $\pm$ .25 mg/dl to 0.92 $\pm$ .20 mg/dl respectively;  $p = 0.25$ ). Serum ALT value (U/L) did not show any significant change. Serum triglyceride level was notably reduced from pre-Ramadan to post-Ramadan visit (159.08 $\pm$ 56.85 mg /dl to 101.33 $\pm$ 63.95 mg/dl;  $P < 0.05$ ). The results of the variations of biochemical parameters of studied participants have been summarized in Table VIII.

### DISCUSSION

This study was conducted upon Bangladeshi type 2 diabetic subjects during the month of Ramadan to assess the pattern of follow-up, medication adjustment and impacts of fasting on clinical and biochemical indicators. The effect of Ramadan fasting on diabetic subjects has been demonstrated in various studies.<sup>20, 21</sup> This study confirmed that well-adjusted patients tolerated Ramadan fasting. Here, the mean of BMI and weight were significantly reduced after Ramadan fasting; this BMI reduction has also been found in some previous works.<sup>22, 23</sup> This was probably due to a decrease in the number of meals (two meals instead of three meals) that contributed to reduced calories intake during Ramadan as compared to pre-Ramadan period. A significant reduction of systolic and diastolic blood pressure was recorded after Ramadan ( $p < 0.001$ ).

A pre-Ramadan visit to the physician decreased the risk of developing hypoglycemia in diabetic patients who intended to fast compared to those who did not go for a medical consultation.<sup>24</sup> EPIDIAR study reported that 62% of patients with type 2 diabetes obtained advice from their healthcare providers before starting to fast and 2% of the patients with type 2 diabetes experienced severe hypoglycemia and 4% experienced severe hyperglycemia requiring hospitalization.<sup>11</sup> Here, all of

the studied participants went for a medical review by their physician before they began fasting.

Regarding use of antidiabetic drugs during Ramadan, metformin is the most prescribed one alone or in combination with other drug(s) or insulin.<sup>25</sup> Sulphonylurea agents and other insulin secretagogue still represent as treatment modalities in Ramadan despite of risk of hypoglycemia and weight gain effects.<sup>26, 27</sup> A study conducted in North-West London among Muslim patients with Type 2 diabetes attending primary care practices, showed that appropriate treatment adjustments can lead to avoidance of significant weight gain and improved glucose control without hypoglycaemia and addition of vildagliptin to metformin therapy during Ramadan in Muslim patients with type 2 diabetes was associated with a reduction in the incidence of hypoglycaemia while compared with sulphonylurea.<sup>28</sup> In this study, we noted that metformin and sulphonylurea was commonly prescribed anti-diabetic drugs all through the study period; used alone or in combination with other oral anti-diabetic drugs (OADs) or insulin. Gliclazide and glimepiride were the most frequently used sulphonylurea-group of drugs. In this study, patients were treated with a stable dose of DPP4 inhibitors (sitagliptin and vildagliptin) through-out the studied period This study also exhibits the use of different regimens of insulin. Premixed insulin was the commonest insulin regimen during study period. With dose adjustment, none of the studied participants experienced severe hyper/hypoglycemia requiring hospitalization or an emergency room visit.

Multiple studies have demonstrated that HbA1c values do not change during Ramadan fasting.<sup>29, 30</sup> Our results revealed a reduction of the mean HbA1c after Ramadan fasting, which was not statistically significant. While it has been found that after fasting, our patients had a significant decrease in FBG from 9.27 to 8.46 mmol/L and prandial blood glucose showed similar trend. A previous investigation showed that the levels of triglycerides decreased at the first week of fasting and increase later towards the end of Ramadan.<sup>31</sup> Here, participants presented a significant reduction in the triglyceride level during post Ramadan period ( $P < 0.05$ ) while creatinine level showed a decreasing tendency ( $P = 0.25$ ).

### Limitations

This study has several limitations. It had no control group. Variables such as physical activity and meal plan that can potentially affect results were not recorded. Only patients with type 2 diabetes were included. The study was conducted in urban area only. Studied participants were asked to monitor their blood glucose at home, but many patients did not follow according to schedule for various reasons such as non-compliance, belief that it may break fast, non-availability of glucometer or lack of family support.

### Conclusion

This study finds that studied participants with T2DM consulted their physician for pre-Ramadan education, counseling and medication adjustment which helped in avoiding severe hypoglycemia or other acute complications during Ramadan fasting. Along with reduction of body weight, BMI, blood pressure and lipid profile, Ramadan fasting appeared to reflect beneficial effects on glycemic status of patients.

**Authors' contributions:** NKQ prepared study design, did data analysis, data interpretation, drafted and edited the manuscript. NA contributed to data analysis, data interpretation and manuscript preparation. ZAL developed the concept, designed the study, edited and reviewed the manuscript. All Authors read and approved the final manuscript.

**Conflict of interest:** Nothing to declare.

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