

Original article

The Effects of Fasting Ramadan on Glycemic Control and BMI in Patients with Type 1 Diabetes treated with insulin pump therapy

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Abstract

Background: Many Moslem patients do observe the fast-during Ramadan. We report our experience with type 1 diabetes patients on continuous subcutaneous insulin infusion during Ramadan. During this time, Muslims refrain from eating, drinking, smoking, sexual intercourse and administering oral drugs from sunrise to sunset daily for 29 to 30 days (Lunar month).

Objectives: This study was designed to evaluate the effect of insulin pump therapy on the metabolic parameters specially the glycated HbA1C, lipid profile and body mass index in(T1) diabetics treated with insulin pumps during the fasting of Ramadan.

Patients and methods: This observational study was conducted in the insulin pump OPD in the diabetes and Endocrinology center located in Tripoli-Libya during the Fasting month in the Year 2017(1438 Hijri). A total of 35 patients were evaluated (24 female &11 males). Data on sociodemographic characters (age, sex, educational level, occupation) as well as Anthropometric measurements were taken. The data was obtained using a face-to-face interview, the measurements were taken using a structured questionnaire, and lastly, blood samples were collected for testing, glycosylated hemoglobin (HbA1c), Lipid profile, urea, and creatinine.

Results: This study included 35 patients with type 1 diabetes mellitus treated with insulin pumps (11 males and 24 females). The mean participant age was 27.80 ± 10.23 years. The mean body mass index (BMI) of the participants was 27.84 ± 9.02 kg/m². All patients have received the same team instructions. Among all participants, the average readings level of HbA1C, low density lipoprotein, high density lipoprotein and triglycerides and were significantly lower after finish of Ramadan as compared with before Ramadan ($P < 0.05$). **Conclusion:** these results revealed that type 1 diabetic patients on insulin pump therapy could fast Ramadan with significant good impact on HbA1c and lipid profile.

Ramadan takes place in the ninth lunar month of the Islamic year calendar and lasts about 29-30 days. Fasting during Ramadan is one of the five pillars of Islam(1). Muslims strictly restrain

ing, ins from eating, drinking, smoking, sexual intercourse and administering oral drugs from sunrise (FAJR) to sunset (MAGREB), which can vary from 11 to 20 hours depending on geographic location and time of the year in that Ramadan occurs(2). Two main meals are eaten per night during the month of Ramadan IFTAR

at sunset and SOHOUR at dawn (3). Normally the Fast is not associated with harmful effects. However, in patients with diabetes mellitus, it could lead to serious complications (4). Religiously and medical societies have generally discouraged individuals with T1DM, in particular adolescents, from fasting and T1DM continues to be listed as a high-risk factor for fasting (1-5). The beneficial effects of intensive glycemic control on reducing the risk of chronic complications in type 1 diabetes were firmly established in the Diabetes Control and Complications Trial (DCCT) (6) and The UK Prospective Diabetes Study (UKPDS) (7). Both continuous subcutaneous insulin infusion (CSII) and multiple daily injection (MDI) therapy are effective means of implementing intensive diabetes management. A review (8) of controlled trials in patients with type 1 diabetes showed that with CSII therapy, the mean blood glucose concentrations and glycosylated hemoglobin (HbA1C) values were either slightly lower than or comparable to those of multiple daily injections method. In patients with type 2 diabetes, 2 studies (9,10) found that insulin pump therapy resulted in a marked improvement in blood glucose concentrations, with a corresponding decrease in HbA1C. The present study was undertaken to assess the effect of insulin pump therapy on the glycemic and metabolic control during Ramadan fasting in young diabetic T1 patients in the diabetes and endocrinology center in Tripoli - Libya.

Patients and methods This is an observational study included 35 participants (11 males and 24 females), with mean age SD 27.80 ± 10.23 years who were recruited from our insulin pump clinic in the diabetes and endocrinology center in Tripoli during the period from 2 weeks before Ramadan and 2 weeks after Ramadan the Hijri year of 1438 (between 28 May to 30 June 2017). A verbal consent was obtained from the participants prior to participation in the study. The research team were recruited to administer the Questionnaires and perform anthropometric

measurements and face to face interview was conducted to fill the questionnaires which composed of Sociodemographic data such as age, sex, address, education level, and occupation. Anthropometric data such as height was measured by using height and weight electronic scale (SECA, Germany), while the patients were standing bare feet and with normal straight posture, and weight was measured in kilograms. BMI was calculated as the Ratio of weight (kg) to the square of height (m). Laboratory investigations before and after Ramadan such as glycated hemoglobin (HbA1C), low density and high-density lipoprotein (HDL and LDL) cholesterol, total cholesterol levels, triglyceride, urea, creatinine and uric acid were measured by using an Integra 400 pulse machine. This group of patients were part of the patients already on follow up in the pump clinic in the diabetes and endocrinology center in Tripoli - Libya. These patients showed interest in fasting the Holy month of Ramadan. The patients were trained on insulin pump programming and carbohydrate counting and started on continuous basal insulin infusion in addition to meal and high blood glucose correction insulin boluses. In our present study we have adjusted the basal insulin dose from the first day of Ramadan by reversing the dose distribution from daytime to evening time so that the maximum dose to be given during the evening eating time and the smallest dose at day fasting time so as the smallest dose at the late hours of fasting day time. Just one hour before breaking the fast we start to increase the basal insulin dose. The patients are instructed to measure their blood sugar before and 2 hours after each meal and at least 4 hourly at the fasting day time. The insulin meal dose is calculated automatically by the pump through use of insulin carbohydrate ratio (ICR) and insulin sensitivity factor (ISF). Patients are also educated to take correction doses by significant hyperglycemia ($PG > 180$). Patients are instructed to cut their fasting if at any day time $PG < 70$

mg% or >300 mg %.also to stop temporary the pump if the blood sugar during day time getting below 100 mg and to resume the pump again if blood sugar raised to>100 mg % .The patients have been asked to seek team medical advice by problems either by phone contact or clinic visit. Laboratory data done before Ramadan and recollected within 2 weeks after Ramadan .Our main aim was to observe the changes in glycemic control through changes of HbA1C at the same time allowing our patients to take part in this very important religious Event with the least acute problems.

Statistical analysis Was done by using the software SPSS version 21. A paired sample Test

was used for comparison between two sets of data. A p-value of<0.05 was considered to indicate a statistically significant difference.

Results From sociodemographic table (1)ofthe 35 participants, 24 (68.6%) were women and 11(31.4%) were men. The mean ± SD age of the participants was 27.80±10.23 year. The mean duration of diabetes was 10.01 ± 3.01years. Most of our participants were single 29 (82.9%) and 5(14.3 %) were married .one participant was widow (2.8%). The majority of participants education level 21(60%) were from university and the rest 14 participates (40%) were from secondary school.25participants (71.4%) live in Tripoli and the rest outside Tripoli.

Table (1) Distribution of demographic characteristics of the participants (N=35).

Variable	Number	Percentage
Age group (mean ± SD) year	27.80±10.23 years	
15-30	14	40 %
31-40	12	34.3 %
≥ 41	9	25.7 %
Gender		
Males	11	31.4%
Females	24	68.6%
Occupation		
Housewife	4	11.4%
Employee	7	20%
Doctor	2	5.7%
Student	22	62.8
Education level		
Secondary	14	40 %
University	21	60 %
Address		
Tripoli	25	71.4%
Outside Tripoli	10	28.6%
Duration of Diabetes mellitus		
1-5 years	5	14.3%
6-10 years	15	42.9%
More than 10 years	15	42.9%
Marital state		
Single	29	82.9%
Married	5	14.3%
Widow	1	2.8%

Table (2) illustrates the biochemical and anthropometric characteristics of the study sample before and after Ramadan fasting.

The mean \pm SD of the glycated HbA1C was significantly lower after Ramadan (7.64 ± 1.23 % vs 7.43 ± 1.12 %, $p = 0.000$), The BMI was significantly increased after Ramadan (27.84 ± 9.02 /kg/m² vs 27.87 ± 9.02 / kg²; $p = 0.000$). LDL – cholesterol has significantly increased after Ramadan (98.41 ± 30.32 mg/dl vs 109.22 ± 26.24 mg/dl; $p = 0.018$) while triglyceride level showed

a significant decrease (79.82 ± 45.71 mg/dl to 76.39 ± 36.81 /dlp = 0.001). Additionally, there was significant reduction in the uric Acid level (3.13 ± 0.73 mg% to 3.08 ± 0.84 mg/dl; $p = 0.000$). both urea and creatinine have decreased significantly from (25.01 ± 18.1 mg/dl to 23.11 ± 12.1 mg/dl $p = 0.04$ versus 0.47 ± 0.15 mg% to 0.46 ± 0.10 mg % $p = 0.007$ respectively).

Table (2) Comparison of mean anthropometric & Biochemical characteristics among patients before and after Ramadan.

Blood Investigation	Before Ramadan (Mean \pm SD)	After Ramadan (Mean \pm SD)	Chang (Paired \pm Value) (95% ci)	P Value
WT	70.45 \pm 18.06 /kg	70.31 \pm 18.04	0.34 to 0.632	0.000
BMI	27.84 \pm 9.02/kg ²	27.87 \pm 9.02 / kg ²	0.20 to 0.136	0.000
HbA1c	7.64 \pm 1.23 %	7.43 \pm 1.12%	0.136 to 0.556	0.000
LDL	98.41 \pm 30.32mg/dl	109.22 \pm 26.24 mg/dl	26.27 to 4.65	0.018
CHOL	152.32 \pm 41.23 mg/dl	158.25 \pm 24.08 mg/dl	47.41 to 22.9	0.50
HDL	56 \pm 18.8 mg /dl	68.25 \pm 24.08 mg/dl	19.51 to 5.43	0.000
TG	79.82 \pm 45.71 mg/dl	76.39 \pm 36.81 mg/dl	11.85 to 18.72	0.001
Urea	25.01 \pm 18.1 mg/dl	23.11 \pm 12.1 mg/dl	11.05 to 10.68	0.04
Creatinine	0.47 \pm 0.15 mg%	0.46 \pm 0.10 mg %	0.05 to 0.68	0.007
Uric Acid	3.13 \pm 0.73 mg%	3.08 \pm 0.84 mg/dl	0.18 to 0.29	0.000

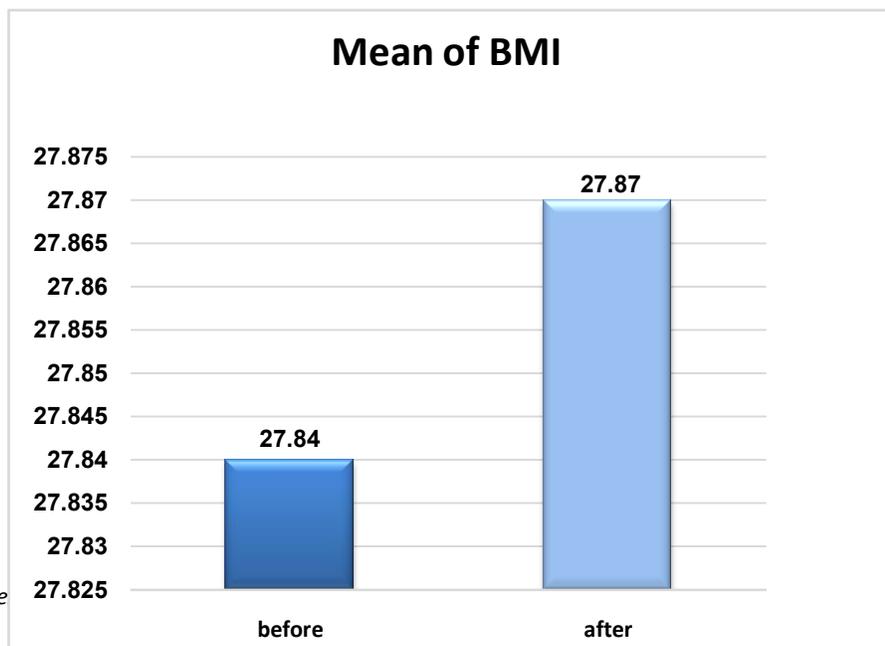


Figure (1). Mean of BMI pre-Ramadan and after Ramadan changes in the participants.

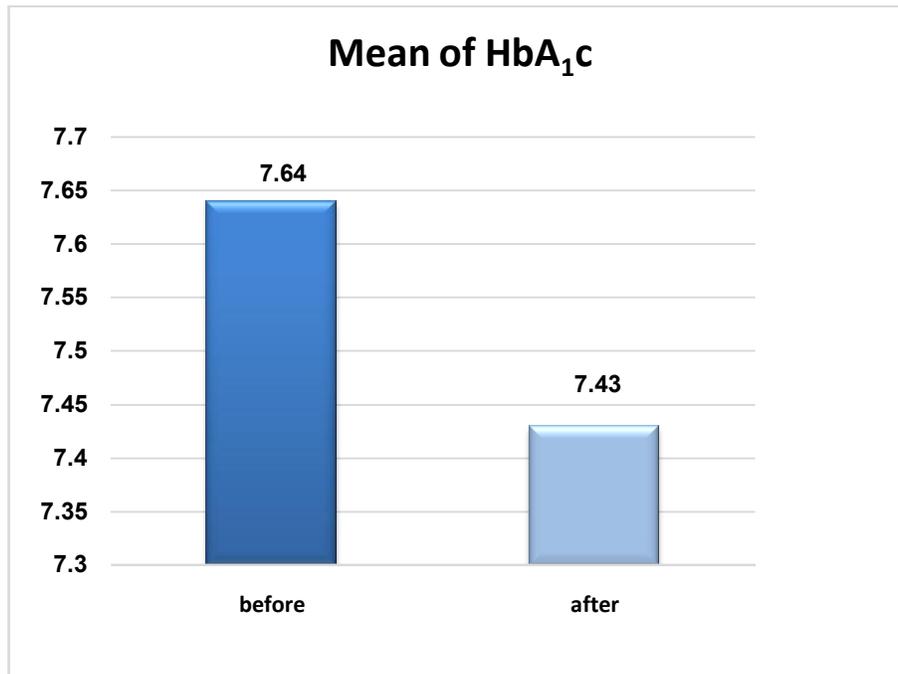


Figure (2). Mean of HbA_{1c} pre-Ramadan and after Ramadan changes in the participants.

Discussion

The use of insulin pump therapy is ever increasing in clinical practice. Several professional bodies recommend use of insulin pump therapy because of the dual advantages of achieving adequate glycemic control coupled with reduced risk of hypoglycemia specially if augmented with rtCGM (real time continuous glucose monitoring) with the option of either threshold or predictive low glucose suspend. Currently, it is recommended as an option when

choosing an insulin delivery method by several reputable organizations such as the National Institute of Clinical Excellence in the United Kingdom, the American Diabetes Association, and the European Association for the Study of Diabetes (8-11). During Ramadan fasting, patients abstain from carbohydrate and calorie intake from sohur to Iftar during the daytime. On the other hand, it is not uncommon for people to indulge in food consumption from

Iftar to sohduring the nighttime period to overcompensate for the daytime fasting. This eating pattern predictably creates two contrasting metabolic profiles in the daytime and nighttime. The two major metabolic problems feared during Ramadan are the potential daytime hypoglycemia due to deprivation of calorie intake and unopposed insulin action and possible hyperglycemia after the breaking of the fast in the evening due to compensatory overeating. These changes can be better managed by an insulin pump-based regimen than by multiple insulin dose injection therapy. Hypoglycemia can be aborted, reduced, prevented, and even more readily treated in pump-treated patients by timely downward adjustments or even totally stopping of insulin delivery from the pump. Such an advantage is not available to those treated with a conventional insulin injection where insulin continues to be released from the site of injection throughout its predetermined duration of action. Any excess insulin action can only be counteracted by intake of carbohydrates. In our study the finding that HbA1c concentration at the end of Ramadan was decreased from the baseline is consistent with results from previously published studies in patients with T1DM and T2DM(12,13,14).In the review of the

literature (13) fasting during Ramadan was found to be well tolerated in T2DM patients who were compliant with their diet and drug intake. The main outcomes of this study was the ability of the patients to fast the Ramadan month without deterioration in the glycemic control. For optimal results it is important that patients in this age group be selected carefully, educated thoroughly and followed diligently by a team of trained professionals. The availability of multidisciplinary diabetes care team with the required skills and experience in pump therapy is critically important(15-16). In our study there was significant increase in the BMI,althoughDiMeglio et al. did not observed significant difference between groups in BMI percentile for age at the end of the study (17). In contrast, Weintrob et al. (18) found a significantly higher BMI SD in the group treated with MDI compared with patients treated with CSII .the increased body weight probably related to the decrease in daily activity in Ramadan due to the fear of attacks of hypoglycemia .In our study there was no significant increase in the total cholesterol level but increase in the LDL-cholesterol level, meanwhile there was significant decrease in the TG level , however previous studies showed mixed results (19,20,21).

Conclusion

In this case study adolescent and adult patients with T1 DM on CSII (insulin pumps) who wishes to fast Ramadan were able to do it with maintained or even slightly improved HbA1c

Recommendations

-this is our second observational study in our short experience period (only 7 years) in using insulin pumps in our hospital. The first study has looked for glycemic change over longer time but this one only during fasting Ramadan. This

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concentration under the supervision of good multidisciplinary working team and follow up program.

study lacks the look on the effect of fasting Ramadan on the risk of hypoglycemia which represent the safety of fasting during Ramadan. We wish that we could observe that in the next nearest chance.

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