



Contents lists available at ScienceDirect

Diabetes & Metabolic Syndrome: Clinical Research & Reviews

journal homepage: www.elsevier.com/locate/dsx



Original Article

Outcome of focused pre-Ramadan education on metabolic and glycaemic parameters in patients with type 2 diabetes mellitus

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ARTICLE INFO

Article history:
Available online xxx

Keywords:

Hypoglycaemia
Education
Diabetes
Ramadan fasting
Egypt

ABSTRACT

Background: Ramadan fasting is associated with the risk of acute complications including hypoglycaemia. Therefore, patients' education before Ramadan and follow up during Ramadan is essential for safe fasting. **Objectives:** To evaluate the effect of pre-Ramadan education program on biochemical parameters and the risk of hypoglycaemia in patients with type 2 diabetes mellitus.

Methods: A prospective interventional controlled design was carried out on 320 Muslim patients with type 2 diabetes. They were divided into 2 groups; the control group (n = 200) who received standard diabetic care and the intervention group (n = 120) who received focused individualized diabetic education sessions before Ramadan. The study was carried out on 3 phases (before, during and after Ramadan). Post-education change of hypoglycaemia risk and biochemical parameters during Ramadan fasting were the primary outcomes.

Results: Fasting blood glucose decreased significantly during, and after Ramadan in both groups (P < 0.001). Hypoglycaemia during fasting occurred in 4.1% of patients in the intervention group vs. 19.5% in the control group. Post Ramadan reduction of HbA1c < 7% increased statistically significantly in the intervention group (from 20.8% of patients before Ramadan to 55.8% after Ramadan). Low-density lipoprotein cholesterol decreased in the intervention group (P = 0.024). The body weight of the patients did not significantly change in both groups.

Conclusion: There was a significant impact of pre-Ramadan educational program on reduction of hypoglycaemic risk and other acute complications, reduction of low-density lipoprotein cholesterol and improvement of high-density lipoprotein cholesterol. Therefore, it is recommended for the fasting patients especially those with high and very high risk during Ramadan.

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1. Introduction

Ramadan fasting represents spiritual habit and religious obligation for Muslims. This generally creates an intense and passionate desire to fast. During fasting, Muslims should abstain from eating and drinking from dawn to sunset. Although sick patients including diabetic patients are excused from fasting, many patients insist to fast.

Diabetes is one of the diseases with high prevalence in Egypt which is considered one of the top 10 countries in the prevalence of diabetes [1]. As fasting is a way of practicing patience rather than creating excessive hardship or safety challenge, the patients with very high and high risk of diabetic complications as described by IDF and Diabetes and Ramadan International Alliance (IDF-DAR)

should not fast [2]. However they insist to fast denying the risks of fasting. Without any medical guidance, these patients' fasting may be associated with many complications including hypoglycaemia, hyperglycaemia with or without the risk of impending ketosis, dehydration, and thrombosis [3].

Ramadan during previous few years was and in the next years will be in the summer months with dry hot weather and long day-time in Egypt. This carries more challenge for fasting diabetic patients. Upper Egypt represents an important geographic part in Egypt with different environmental and cultural conditions and there is a lack of studies evaluating the effect of Ramadan fasting on diabetic patients in this region. Therefore, the aim of this study was to evaluate the impact of pre-Ramadan education on risk of hypoglycaemia, glycaemic control, and other clinical and metabolic parameters among a group of type 2 diabetic patients in clinics of Assiut university hospital, Assiut, the capital of Upper Egypt.

The current guidelines recommend that diabetic patients should be educated to reduce the risk of acute diabetic complications [2,4,5]. The self-monitoring of blood glucose,

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modification of medication dose and timing, dietary regulations and physical activity encouragements are the main components of the educational programs. These educational programs should be individualized.

2. Methods

The study was carried out in Assiut university hospital outpatient clinics of Internal Medicine department (diabetes and endocrinology unit) during the period between May 2016 and July 2017. Patients were recruited from daily follow-up in the clinics using the convenience sampling technique. Patients were informed about the study during their regular care before the fasting.

2.1. The inclusion criteria

The inclusion criteria were Muslim patients with type 2 diabetes mellitus who intended to fast Ramadan.

2.2. The exclusion criteria

The exclusion criteria were the patients with serious comorbidities such as recent acute coronary syndrome or severe hepatic/renal disease, elderly patients with alertness problems, newly diagnosed type 2 diabetic (<3 months) patients, patients with recent hospitalization for diabetic ketoacidosis or severe hyperglycaemia a month prior to the start of the fast, hypoglycaemia during the past month and patients who received short term corticosteroid therapy.

2.3. Design

An interventional controlled design was carried out on 320 Muslim diabetic patients. Patients were divided into 2 groups. The first group was Muslim diabetic patients who fasted Ramadan with standard diabetic care (n = 200 patients). The second group was Muslim diabetic patients who fasted Ramadan with focused pre-Ramadan education (n = 120 patients). The study was done in three phases: the first phase (2–3 weeks before Ramadan), the second phase (the third week of Ramadan), and the third phase (4 weeks after Ramadan)

2.4. Data

The data of the patients were collected after their consent to participate in the study and through a semi-structured questionnaire, which included: [age, sex, nutritional habits, degree of physical activity of the patient] [duration of diabetes, current treatment and medical complication of diabetes] [history of hyperglycaemia, diabetic ketoacidosis or hypoglycaemia in the 3 months before the start of Ramadan and history of fasting during previous Ramadan]. In each phase of the 3 phases, Anthropometric measures including (Body weight, waist circumference and Body mass index), blood pressure and laboratory investigation including (Fasting blood glucose, Complete blood count, Serum creatinine and blood urea, Serum uric acid level and Lipid profile) were collected. HbA1c were measured in the first phase and third phase of the study. At the end of fasting, the number of fasting days and causes of breaking the fast were reported.

2.5. Intervention

The second group of the patients was received an educational program which was carried out in the outpatient clinics 6–8 weeks before Ramadan and through individual sessions lasting 20–30 min. The educational program focused on assessment and

adjustment of the patient's diet according to the individual's requirement, encouraging the patients to continue their usual physical activities and to avoid heavy physical activity during fasting, confirming the importance of frequent blood sugar measurement during the day, adjustment of medication according to the recommendation. Every patient was given Glucometer and a pack of 100 strips and was advised to chart his/her blood glucose in a designed chart at least twice daily (one during the fasting period before Iftar and the second 2 h post Iftar) and when he/she developed symptoms of hyperglycaemia or hypoglycaemia. They were informed about the importance of breaking the Fast when blood glucose was less than 70 mg/dl or more than 300 mg/dl or with occurrence of symptoms of hyperglycaemia or hypoglycaemia or dehydration.

At the end of fasting, each patient was inquired about how this education program affected his /her fasting.

2.6. Assessment criteria of daily blood glucose measurement chart

Hypoglycaemia was classified according to American Diabetes Association into:

- Glucose alert value: Blood glucose \leq 70 mg/dl (3.9 mmol/L).
- Clinically significant hypoglycaemia: $<$ 54 mg/dl (3.0 mmol/L).
- Severe hypoglycaemia: when hypoglycaemia associated with severe cognitive impairment requiring external assistance for recovery and there was no specific glucose threshold [6].

Hypoglycaemia was also classified into

(a) Symptomatic hypoglycaemia. (b) Biochemical hypoglycaemia (blood glucose level = 54–70 mg/dL) without symptoms.

Hyperglycaemia was categorized into

- Severe hyperglycaemia (blood glucose level $>$ 299.88 mg/dL)
- Moderate hyperglycaemia (blood glucose level = 250.92–299.88 mg/dL).
- Mild hyperglycaemia (blood glucose level = 199.98–249.84 mg/dL). *Diabetic ketoacidosis and hyperglycaemic hyperosmolar state* were diagnosed according to the standard guidelines [7].

2.7. Statistical analysis

Data were collected and analysed using SPSS (Statistical Package for the Social Science, version 20, IBM, and Armonk, New York). Continuous data was expressed in the form of mean \pm SD while nominal data was expressed in the form of frequency (percentage). Chi²-test was used to compare the nominal data of different groups in the study while student *t*-test was used to compare mean of different two groups and ANOVA test for more than two groups. Multivariate regression analysis was used to determine the independent risk factors for HbA1C and fasting blood glucose. A p-value of less than 0.05 was considered statistically significant.

2.8. Ethical consideration

The study was approved by the Faculty's Ethics Committee and permission was obtained from the Ethics Committee who assured that confidentiality would be maintained and ethical principles would be followed.

3. Results

The study included 320 patients with diabetes who were divided into two groups; 200 patient in control group and 120

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