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Original article

Impact of Ramadan Focused Education Program on medications adjustment for patients with type 2 diabetes in a primary health care institution in Saudi Arabia

Ayla M. Tourkmani [a,*], Turki J. Alharbi [a], Abdulaziz M. Bin Rsheed [a], Abdulrhamn N. AlRasheed [a], Saad M. AlBattal [a], Osama Abdelhay [a], Mohamed A. Hassali [b], Sultan I. Faya [a], Ebrahim S. Assiri [a], Khalid I. Al Ghishiayan [a], Alian A. Alrasheedy [c], Mostafa AF. Abbas [a]

[a] Family and Community Medicine Department, Chronic Diseases Center, Prince Sultan Military Medical City, Riyadh, Saudi Arabia
[b] Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, Penang, Malaysia
[c] Department of Pharmacy Practice, College of Pharmacy, Qassim University, Qassim, Saudi Arabia

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ABSTRACT

Aims: To examine the impact of Ramadan Focused Education Program (RFEP) on medications adjustment in type 2 diabetes patients in Ramadan.
Methods: This is a controlled, intervention based study. It was run on three phases: before, during, and after Ramadan on 262 type 2 diabetes patients. The intervention group (n = 140) received RFEP on medications doses & timing adjustment before and after Ramadan, while the control group (n = 122) received standard care.
Results: The dose of insulin glargine was reduced from 42.51 ± 22.16 at the baseline to 40.11 ± 18.51-units during Ramadan (p = 0.002) in the intervention group while it remained the same in the control group before Ramadan and during Ramadan (38.51 ± 18.63 and 38.14 ± 18.46, P = 0.428, respectively). The hypoglycemia score was 14.2 ± (8.5) pre-Ramadan in the intervention and reduced to 6.36 ± 6.17 during Ramadan (p < 0.001) while in the control group, no significant changes were noted before and during Ramadan (14.01 ± 5.10 versus 13.46 ± 5.30).
Conclusions: Ramadan Focused Education Program done at a primary healthcare setting had a positive impact on medication adjustment for dose and timing during fasting in Ramadan in diabetic patients, and it can be a useful tool to achieve better outcomes; less hypoglycemia and safe fasting among T2D patients during Ramadan.

1. Introduction

Lack of appropriate education before Ramadan could result in wrong practices [1]. Acute complications are often seen among diabetic patients who fast during Ramadan without appropriate medical guidance [2]. Current guidelines recommend that diabetic patients should have counseling and education about the need to modify medication dosage and timing, dietary habits, physical activity and self-monitoring of blood sugar, to reduce the risk of acute diabetic complications [3–5]. The frequency of hypoglycemia in T2D is different by the type of treatment received [6]. In a cross-sectional study among more than 1000 T2D patients, the prevalence of hypoglycemic symptoms was 12% in patients on a diet alone, 16% in patients using oral anti-diabetic drugs alone, and 30% among those using insulin [7]. In the EPIDIAR study, one-fourth of patients treated with oral anti-diabetic drugs were able to change their treatment dose [8].

The healthcare providers should set individualized glycemic target while avoiding strict glycemic control, particularly in elderly

* Corresponding author.
E-mail addresses: aylatourkmani@gmail.com (A.M. Tourkmani), TJALHARBI@psmmc.med.sa, turkifcm@yahoo.com (T.J. Alharbi), AMBINRASHEED@psmmc.med.sa (A.M. Bin Rsheed), analrasheed@psmmc.med.sa (A.N. AlRasheed), salbattal@psmmc.med.sa (S.M. AlBattal), osamaabdelhay@gmail.com (O. Abdelhay), azmihassali@gmail.com (M.A. Hassali), sfaya@psmmc.med.sa (S.I. Faya), iassiri@psmmc.med.sa (E.S. Assiri), Kghishian@psmmc.med.sa (K.I. Al Ghishiayan), alian-a@hotmail.com (A.A. Alrasheedy), MKOFI@psmmc.med (M.AF. Abbas).

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patients with complicated or advanced T2D [9]. The physician should aim to achieve the goals of treatment with minimal adverse effects [10] Assessment factors include having unplanned meal, practicing unusual exercise, using multiple medications, and associated comorbidities [11].

We aimed to examine the impact of Ramadan Focused Education Program (RFEP) on medication use and hypoglycemia.

2. Methodology

2.1. Subjects, material, and methods

Setting: The study was conducted in Al-Wazarat Healthcare Center. This is a large family medicine center located in Riyadh, Saudi Arabia.

Study design: This is a controlled interventional study. It was conducted between June 2013 and February 2014. The study was done in three phases: first phase (2–3 weeks before Ramadan, enrollment), second phase (the third week of Ramadan), and third phase (4 weeks after Ramadan, HbA1c measured 12 weeks after Ramadan).

Hypothesis. Patients with type 2 DM who received RFEP on medication adjustment would have less chance of hypoglycemia compared to those who did not receive. This study is part of a large project aiming to improve the patient care provided to the diabetic patients who are fasting during Ramadan. A detailed methodology is provided elsewhere [10].

The intervention group received RFEP before Ramadan while the control group received standard diabetic care as per the American Diabetes Association standard of medical care. The RFEP was carried out by the clinical pharmacist, primary care physician, and dietician, through individual and group sessions (as appropriate) for 40–60 min. The educational intervention included audio-visual material and brochures focusing on diabetes self-care, signs and symptoms of hyper- and hypoglycemia, self-monitoring of blood glucose, and management of acute complications. Patients were encouraged to frequently self-monitor for glycemia and to immediately end their fast in case of hypoglycemia (blood glucose <60 mg/dl). Patients were also advised to adjust the dosage and timing of oral hypoglycemic agents and insulin.

Patient Population: Patients with T2DM who were receiving care at WHC at the time of the study and were receiving oral antidiabetic medications or insulin. Exclusion criteria included serious comorbidity as unstable angina or severe hepatic/renal disease, elderly patients with alertness problems, newly diagnosed T2DM (<3 months), hypo-glycemia during last month or unawareness of hypoglycemia. The main outcome of the study was the change in anti-diabetic medication use and hypoglycemia score.

Sampling and recruitment: Patients were recruited from the clinical pharmacy clinic using convenience sampling technique. The study controls were recruited after completing the recruitment of the patients in the intervention group.

Data collection tools: Data were collected using a structured questionnaire which included socio-demographic information, duration of diabetes, current anti-diabetic medications and hypoglycemia questionnaire introduced by the Hypoglycemic Health Association (HHA) of Australia. Face and content validity of the questionnaire was done by three experts of diabetes management. Bidirectional translation (Arabic, English) of the questionnaire including the hypoglycemia part was done. The pilot was done on 15 participants, and the feedback was used to improve the understanding of the questionnaire. Reliability of the hypoglycemia questionnaire was found to be satisfactory (Cronbach's alpha of 0.873).

2.2. Statistical methods

Results were presented as the mean and standard deviation for continuous variables and frequency and percentages for categorical variables. Patients' demographic, clinical, and biomedical information were presented as mean and standard deviation for continuous variables, and frequency and percentages for categorical variables. To examine the significance of the changes in glycemic control and other study outcomes across the three phases of the study, repeated measures analysis of variance was run for continuous variables. For the repeated measures analysis of variance, the P-value of Wilks' Lambda is reported and when statistically significant, a post hoc analysis was performed using Bonferroni test to adjust for multiple comparisons. For categorical variables, Mantel–Haenszel chi-square was used. To examine the difference in study outcomes between the intervention and control groups during the study phases, independent *t*-test (or its equivalent Mann–Whitney *U*-test) was used for continuous variables and chi-square for categorical variables. SPSS software (release 20.0, IBM Corporation, Armonk, NY, USA) was used for all statistical analyses.

3. Results

Table 1 shows the demographic and clinical characteristics of both groups. It showed that the average duration of diabetes was approximately 13 years in both groups.

Table 2 summarizes the impact of RFEP on the number of medication by types - used during the three phases of the study. The patients in interventions group were using many different types of insulin more than control group (1.71 ± 0.57 [Median (IQR) = 2 [1,2]]) versus 1.14 ± 0.55 [Median (IQR) = 1 (1-1]) respectively, $p < 0.001$). The number of insulin types used remained consistently higher in the intervention group compared to control group at the three phases of the study ($p < 0.001$), without any statistically significant changes within each group ($p = 0.331$ in the intervention group and $p = 0.063$ in the control group. Many patients in both intervention and control group were on one type of medication (0.97 ± 0.55 [Median (IQR) = 1 (1-1]) versus 0.88 ± 0.47 55 [Median (IQR) = 1 (1-1]) respectively, $p = 0.140$). The number of oral anti-diabetic medications used were similar in both groups at baseline ($p = 0.140$) and remained constant during the study without significant changes ($p = 0.874$ for the intervention group and $p = 0.438$ for the control group).

Table 3 summarizes the impact of RFEP on medications doses and hypoglycemia score during the study phases. Both study groups were using oral antidiabetic medications, particularly metformin, gliclazide, glibenclamide, and pioglitazone. No dose adjustments were made in gliclazide and pioglitazone in both groups. Regarding the doses of metformin, they were slightly reduced during Ramadan, but these dose adjustments were not statistically significant ($P = 0.063$). In the control group, the doses were higher compared to pre- and during Ramadan ($P = 0.002$). For insulin Aspart, the doses remained the same during two phases in the intervention ($P = 0.882$) while in the control group it was reduced during Ramadan and then increased again after Ramadan ($P = 0.006$). For the glargine, in the intervention group, the doses were reduced during Ramadan and then increased again after Ramadan ($P = 0.002$). There were no statistically significant changes in the control group ($P = 0.428$). For insulin Mixtard, in the intervention group, the doses were reduced during Ramadan and then increased after Ramadan ($P = 0.002$) while in the control group there were no statistically significant changes ($P = 0.295$).

For the impact of RFEP on hypoglycemia score. The mean of hypoglycemia scores before, during and after Ramadan were 14.21,

Table 1
Baseline demographic and clinical characteristics in the intervention and control groups.

	Intervention (n = 140)	Control (n = 122)	Test value	p-value
	Mean ± SD N (%)	Mean ± SD N (%)		
Age				
Mean ± SD	55.12 ± 12.76	56.06 ± 11.08	t = 0.630	0.530
Gender				
Male	56 (40.0%)	41 (33.6%)	$X^2 = 1.143$	0.285
Female	84 (60.0%)	81 (66.4%)		
Residence				
Riyadh	120 (85.7%)	114 (93.4%)	$X^2 = 4.079$	0.043*
Outside Riyadh	20 (14.3%)	8 (6.6%)		
Job status				
Unemployed	65 (46.4%)	15 (12.3%)	$X^2 = 35.809$	<0.001*
Working	75 (53.6%)	107 (87.7%)		
Body weight	84.16 ± 18.04	81.01 ± 17.71	t = 1.395	0.164
Body mass index (BMI)				
Mean ± SD	32.93 ± 6.70	32.71 ± 7.14	t = 0.250	0.803
Blood pressure (BP)				
Hypertension (>130/80)	96 (68.6%)	87 (71.3%)	$X^2 = 0.232$	0.630
Systolic BP	130.14 ± 13.85	130.12 ± 15.40	t = 0.011	0.991
Diastolic BP	73.34 ± 8.94	72.98 ± 8.88	t = 0.319	0.750
Diabetes & its management				
Duration (years)	12.95 ± 8.39	12.86 ± 7.61	U = 0.092	0.927
On oral medications	118 (84.3%)	101 (82.8%)	$X^2 = 0.107$	0.744
On insulin	134 (95.7%)	111 (91.0%)	$X^2 = 2.404$	0.121
Number of oral medications	0.97 ± 0.55	0.88 ± 0.47	U = 1.479	0.140
Number of insulin types	1.71 ± 0.57	1.14 ± 0.55	U = 8.307	<0.001*
Hypoglycemia score	14.21 ± 8.50	14.01 ± 5.10	t = 0.234	0.815
HbA1c	9.79 ± 1.89	10.04 ± 1.47	t = −1.196	0.233
Lipid profile				
LDL cholesterol	2.41 ± 0.91	2.53 ± 0.86	t = −1.041	0.299
HDL cholesterol	1.14 ± 0.30	1.14 ± 0.30	t = −0.075	0.940
Total cholesterol	4.35 ± 1.13	4.42 ± 1.27	t = −0.475	0.635
Triglycerides	1.62 ± 0.79	1.86 ± 1.48	t = −1.665	0.097

X2: chi-square test, t: student t-test, U: Mann–Whitney *U* test.

Table 2
Impact of RFEP on medication use during the study phases in the intervention and control groups.

Variable	Pre-Ramadan	During Ramadan	Post-Ramadan	Phase difference
	Mean ± SD	Mean ± SD	Mean ± SD	p-value
	Median (IQR 1-3)	Median (IQR 1-3)	Median (IQR 1-3)	
Number of oral antidiabetic drugs				
Intervention	0.97 ± 0.55	0.99 ± 0.57	0.98 ± 0.57	0.874
	1 (1-1)	1 (1-1)	1 (1-1)	
Control	0.88 ± 0.47	0.84 ± 0.46	0.89 ± 0.53	0.438
	1 (1-1)	1 (1-1)	1 (1-1)	
Group difference	*P* = 0.140	*P* = 0.023*	*P* = 0.212	
Number of insulin types				
Intervention	1.71 ± 0.57	1.64 ± 0.63	1.64 ± 0.61	0.331
	2 (1-2)	2 (1-2)	2 (1-2)	
Control	1.14 ± 0.55	1.07 ± 0.53	1.11 ± 0.52	0.063
	1 (1-1)	1 (1-1)	1 (1-1)	
Group difference	*P* < 0.001*	*P* < 0.001*	*P* < 0.001*	

*Statistically significant difference at p < 0.05.

6.36, and 5.44 in the intervention group, respectively (p < 0.001) and 14.01, 13.46, and 9.27 in control group, respectively (p < 0.001).

4. Discussion

The participants in our study were having a poor glycemic control. For the intervention group, medications dose adjustments were made throughout the three study phases especially for glargine and Mixtard insulin. However, no adjustments were made for Aspart insulin as it does not require the adjustment in Ramadan. Our finding is similar to the findings from the study of Yeoh et al. (2015) in which medications were adjusted to avert hypoglycemia [12].

The use of oral anti-diabetics and insulin in the intervention group were done as per the clinical guidelines. This helped in reducing the risk of hypoglycemia and achieving or maintaining the glycemic control [3,13].

The current finding showed a beneficial impact of FERP on the risk of hypoglycemia. Almost all the previous studies that examined the impact of such programs showed the protective effect on the risk of hypoglycemia [14–17]. For example, Pre-Ramadan focused education among UK Muslim patients with T2D was associated with almost 60% reduction in hypoglycemia during Ramadan compared with the four-fold increase among controls [14].Similarly, a prospective study in Pakistan showed that the majority of outpatients who attended two educational sessions on

Table 3
Impact of RFEP on medication doses and hypoglycemia score during the study phases in the intervention and control groups.

Variable	Pre-Ramadan	During Ramadan	Post-Ramadan	Phase difference
	Mean ± SD	Mean ± SD	Mean ± SD	p-value
Dose of metformin (gm)				
Intervention	2.02±0.53	1.96±0.51	1.87±0.57	0.063
Control	2.13±0.27[#]	2.09±0.27[$]	2.18±±0.27[#$]	0.002*
Group difference	$P = 0.026$*	$P = 0.050$	$P < 0.001$*	
Dose of Aspart (IU)				
Intervention	61.78±42.07	62.84±39.24	61.11±36.68	0.882[a]
Control	56.70±42.58[#]	52.23±40.17[#$]	56.61±42.72[$]	0.006*[a]
Group difference[b]	$P = 0.861$	$P = 0.203$	$P = 0.194$	
Dose of glargine (IU)				
Intervention	42.51±22.16	40.11±18.51[#]	45.31±23.43[#]	0.002*
Control	38.51±18.63	38.14±18.46	38.47±18.55	0.428
Group difference	$P = 0.334$	$P = 0.534$	$P = 0.153$	
Dose of Mixtard (IU)				
Intervention	79.67±31.78	75.26±31.85[#]	86.19±35.60[#]	0.002*
Control	65.38±29.56	64.75±30.78	65.82±32.30	0.295
Group difference	$P = 0.003$*	$P = 0.329$	$P = 0.011$*	
Hypoglycemia score				
Intervention	14.21[#$]±8.50	6.36[#] ± 6.17	5.44[$]± 5.55	<0.001*
Control	14.01[#] ± 5.10	13.46[$] ± 5.30	9.27[#$] ± 4.65	<0.001*
Group difference	$P = 0.815$	$P = <0.001$*	$P = <0.001$*	

(* - [#,#] – [$,$] [^,^]) Statistically significant difference at $p < 0.05$.
[a] Friedman's test.
[b] Mann Whitney test. IU = international unit.

drug dosage and timing alteration, glucose monitoring, did not have any serious acute diabetic complications during Ramadan [15]Additionally, hypoglycemia was less frequently seen during Ramadan among fasting diabetic patients in UAE who received pre-Ramadan targeted education compared with their control counterparts (27% versus 6%) [16]. The education-directed modification in lifestyle and medication (type, dose, and timing) may have resulted in minimizing the risk of acute complications in our patients [17].

5. Conclusion

Ramadan Focused Education Program (RFEP) done at a primary healthcare setting had a positive impact on medication adjustment for dose and timing during fasting in Ramadan in diabetic patients, and RFEP can be a useful tool to achieve the better outcome; less hypoglycemia and safe fasting among T2D patients during Ramadan.

6. Limitations

The lack of randomization in the current study may have resulted in unwanted differences between the two groups at enrollment. For example, there were some significant differences between the two groups in the percentages of those who had targeted hypoglycemic score (<8) and targeted glycemic control (<7). Additionally, there was a higher proportion of patients in the intervention group who were living outside Riyadh compared with the control group. Moreover, patients in the intervention group had more mixed types of insulin and hence had more tendency to hypoglycemia. However, overall, we believe that study results are robust.

Declarations

Ethics approval and consent to participate

The approval was taken from the research ethics committee –Prince Sultan Military Medical City (PSMMC). Informed consent was taken from each patient who agrees to participate and fulfills the inclusion criteria.

Consent to publish

The findings of this manuscript has not been previously published and is not under consideration in any other peer-reviewed journal. No part of this manuscript has been presented at any workshop/conference. No conflict of interest, financial or other, exists.

Competing interest

We declare that we don't have any conflict of interest.

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Authors' contributions

All authors contribute an all steps of the research.

Disclosure statement

The authors have nothing to disclose.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.dsx.2018.07.012.

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