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Fasting experience of patients with Type 2 diabetes mellitus on insulin therapy during Ramadan: VISION Ramadan substudy

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ABSTRACT

Aims: To describe the characteristics and fasting experience of a subgroup of patients in the VISION study who initiated insulin therapy and chose to fast during Ramadan, and to discuss the VISION Ramadan substudy data in the context of previous Ramadan studies.
Methods: The VISION study was a prospective, non-interventional, observational study of adult patients with Type 2 diabetes mellitus in 6 countries in the Western Pacific, Middle East and North Africa, receiving insulin injection therapy for the first time. In this VISION Ramadan substudy, fasting data was collected during Ramadan 2014 and 2015.
Results: Of 1617 patients in the VISION study, data was collected for 357 patients who chose to fast during Ramadan. At baseline, mean HbA1c was 10.1%, duration of diabetes was 8.8 years, and mean BMI was 30 kg/m^2. All patients with non-missing data (n = 169) received advice on fasting during Ramadan. The majority of patients fasted for the full month of Ramadan, and around one-third of patients fasted outside Ramadan.
Conclusions: Here we provide an update on the characteristics and Ramadan experience of patients with Type 2 diabetes mellitus who initiated insulin therapy and chose to fast during Ramadan. There is still a need to explore patient's experience during fasting, and identify and address methods to better help manage those patients.

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1. Introduction

Prevalence of diabetes is increasing worldwide, particularly in Muslim-majority countries [1]. Fasting during Ramadan is an obligatory practice for healthy adult Muslims. Despite discouragement from health care providers (HCPs) and exemptions for people with serious medical conditions, most Muslim patients with Type 2 diabetes mellitus choose to fast during Ramadan [1].

While there remains a lack of randomised-controlled studies to inform the management of patients with Type 2 diabetes mellitus during Ramadan, observational studies do provide important information on the characteristics, experience and care of fasting patients [1]. There is a need to explore patient's experience during fasting, and to identify and address methods to better help manage those patients. Two large multi-country studies examined patient experience during Ramadan. EPIDIAR was a retrospective, cross-sectional survey conducted in 13 predominantly Muslim countries over Ramadan in 2001 [2]. The CREED retrospective observation study in 13 countries, including predominantly Muslim countries and European countries, collected data over Ramadan in 2010 [3,4]. These and other studies report patient characteristics and experience during Ramadan, as well as characteristics of patient care such as guidelines followed by HCPs and Ramadan-focused education programmes [5].

Results of an 18-month, non-interventional study Verifying Insulin Strategy and Initial Health Outcome aNalysis (VISION) have been previously reported [6,7]. Here we present data from a subpopulation of patients who decided to fast during Ramadan, and discuss the data in the context of the previous Ramadan studies.

2. Research design and methods

The VISION study design has been described previously by Jabbar and colleagues (2018). The study was carried out in accordance with the Declaration of Helsinki and the International Conference of Harmonisation – Good Clinical Practice, and was approved by the ethical review boards at each participating site. Written consent was obtained from patients following the decision to initiate insulin therapy. Adult patients (≥18 years of age) with Type 2 diabetes mellitus were included if they had a scheduled clinical visit during the study recruitment period, when the decision to initiate insulin therapy was made. Patients were enrolled from April 2014, and prospective data collected until November 2016. If patient data was not collected during Ramadan 2014, data was collected for these patients during Ramadan 2015. Results presented here are combined data captured during Ramadan 2014 and 2015.

Patients who decided to fast during Ramadan, were asked to record data in a Ramadan diary. Data collected included confirmation of fast, days fasted and Ramadan related education method. Patients who intended to travel during Ramadan, or who had initiated insulin within 3 months of the start of Ramadan, were excluded from the Ramadan data collection. Data were recorded at baseline, at each of the 3 follow-up normal care visits, and at visits before and after Ramadan.

3. Results

In the VISION study, of 1617 patients who were initiated on insulin treatment, 357 patients intended to fast during Ramadan and were included in the Ramadan substudy and completed at least 1 Ramadan diary (Algeria, n = 73; Egypt, n = 165; Saudi Arabia, n = 50; UAE, n = 1; Malaysia, n = 67; Philippines, n = 1). Of these patients, data was captured for a visit pre-Ramadan in 170 patients, and for a visit post-Ramadan in 121 patients. Data was available both pre- and post-Ramadan visits for a total of 112 patients. Despite available guidelines and education, there was a gap in HCPs and patients recording fasting related data during Ramadan.

Patient demographic information is presented in Table 1 and patient clinical features and fasting experience are presented in Table 2. The majority (72.8% [n = 252]) of patients had an HbA1c ≥ 9%, considered high risk by Diabetes and Ramadan guidelines, however, these patients still decided to fast [8]. The data indicated that 47.9% (n = 81/169 with non-missing values) of patients received informal teaching on how to manage their Type 2 diabetes mellitus during Ramadan, 48.5% (n = 82/169 with non-missing values) attended institutional structured education, and 3.6% (n = 6/169 with non-missing information) underwent "managing diabetes during Ramadan conversation map sessions".

In this cohort, approximately one-third of 252 patients reported fasting outside of Ramadan, with 26.4% (n = 24/91 with non-missing values) fasting weekly, and 28.6% (n = 26/91 with non-missing values) fasting monthly. Although the risk category for the 37.1% (n = 13/35 with non-missing values) of patients who needed to break their fast is not known, per the inclusion criteria, all patients were on insulin.

4. Discussion

The VISION Ramadan substudy analysed data from patients with Type 2 diabetes mellitus in 6 countries in the Western Pacific, North Africa and Middle East. These patients initiated insulin therapy and then chose to fast during Ramadan in 2014 or 2015, as their first Ramadan after starting insulin. In addition to the VISION data, Tables 1 and 2 present data from patients with Type 2 diabetes mellitus in the EPIDIAR (Ramadan 2001) and CREED (Ramadan 2010) studies, allowing comparisons between the different patient populations over a 15 year timescale (2001–2015) [2,3]. Of the 6 countries included in the VISION Ramadan substudy, 4 were also included in the EPIDIAR study (Algeria, Egypt, Kingdom of Saudi Arabia, and Malaysia), and 4 in the CREED study (Algeria, Kingdom of Saudi Arabia, United Arab Emirates, and Malaysia).

Across the 3 studies, a similar proportion of patients fasted during Ramadan, although reasons for breaking the fast were not reported in EPIDIAR or CREED, and were not collected in the VISION study. Of the 357 patients in the VISION substudy,

Table 1 – Summary of baseline demographics of patients in the EPIDIAR, CREED and VISION Studies.

	EPIDIAR Study[2] Patients with Type 2 diabetes mellitus (N = 11173)	CREED Study[3] Patients with Type 2 diabetes mellitus (N = 3250)	VISION Study Ramadan Population (N = 357)
Countries Included in the Study	Algeria, Bangladesh, Egypt, India, Indonesia, Jordan, Lebanon, Malaysia, Morocco, Pakistan, Kingdom of Saudi Arabia, Tunisia, and Turkey	India, Indonesia, Malaysia, France, Germany, UK, Turkey, Kingdom of Saudi Arabia, Kuwait, United Arab Emirates, Algeria, Morocco, Tunisia	Algeria, Egypt, Kingdom of Saudi Arabia, United Arab Emirates, Malaysia, Philippines
Ramadan year	2001	2010	2014 and/or 2015
Age, mean (SD) years	54.0 (11.0)	56.9 (10.7)	53.4 (8.97)
Female, %	51.0	51.5	54.3
Weight, mean (SD) Kg	72.4 (14.7)	77.2 (15.2)	80.1 (14.98) [n^* = 333]
BMI, mean (SD) Kg/m^2	27.2 (4.9)	28.7 (5.5)	30.0 (4.88) [n^* = 322]
Duration of Diabetes, mean (SD) years	7.6 (5.8)	8.4 (6.3)	8.8 (5.11) [n^* = 355]
HbA1c, mean (SD) %	NA	7.6 (1.6)	10.1 (1.64) [n^* = 346]
Education Highest Level Attained, %			
No Formal Education	51.0	NA	5.6 (n = 20)
Minimum Mandatory Required Level of Education	NA	NA	30.5 (n = 109)
Secondary or university level/higher education	49.0	NA	59.4 (n = 212)
Primary Occupation, %			
Unemployed	NA	NA	44.5 (n = 159)
Active/Manual worker	53.0	28.3 (n = 915)	NA
Non-active worker (e.g. office worker)	47.0[a]	21.9 (n = 709)	NA
Full-time employed (activity unknown)	NA	NA	38.7 (n = 138)
Retired	NA	25.0 (n = 810)	10.1 (n = 36)
Student	NA	0.2 (n = 5)	0.0 (n = 0)
Tobacco Products Use, %			
Non smoker	80.0	NA	72.8 (n = 260)
Former smoker	NA	NA	9.5 (n = 34)
Current smoker	20.0	NA	14.6 (n = 52)

N = total population size; n = number of patients; n^* = number of patients with non-missing values; (%) = percentage based on total number of patients; (%*) = percentage based on number of patients with non-missing values.

[a] Percentage of non-active worker calculated from patients that were employed.

Table 2 – Summary of clinical features and fasting experience of patients in the EPIDIAR, CREED and VISION studies.

	EPIDIAR Study[2] Patients with Type 2 diabetes mellitus (N = 11173)	CREED Study[3] Patients with Type 2 diabetes mellitus (N = 3250)	VISION Study Ramadan Population (N = 357)
Medical History, n (%)			
Hypertension	5457 (48.8)	2020 (62.1)	195 (54.6)
Diabetic Neuropathy	3101 (27.8)	643 (19.8)	135 (37.8)
Dyslipidemia	3633 (32.5)	1840 (56.6)	116 (32.5)
Cardiovascular Disease	1632 (14.6)	334 (10.3)	45 (12.6)
Diabetic Retinopathy	2197 (19.7)	404 (12.4)	41 (11.5)
Diabetic Nephropathy	1354 (12.1)	360 (11.1)	25 (7.0)
Peripheral arterial disease	1117 (10.0)	111 (3.4)	8 (2.2)
Fasting During Ramadan, %	78.7	63.6 (n = 2043)	71.1* (n* = 254)
Number of Days Fasting	27 (average)	27.2 (SD = 6.0)	26.6 (mean) (SD = 4.92) [n* = 254]
Do you Fast Outside of Ramadan?			
Yes, n (%)	NA	967 (29.9)	92 (36.5*) [n* = 252]
Advice given to fasting patients, %	62	96.2 (n = 478)	100* (n* = 169)

N = total population size; n = number of patients; n* = number of patients with non-missing values; (%) = percentage based on total number of patients; (%*) = percentage based on number of patients with non-missing values.

254 patients with non-missing data reported fasting during Ramadan. For the 103 patients with missing data, it is not known whether patients did or did not fast, nor the reasons for not-fasting. In all 3 studies, patients reported fasting for about 27 days. A similar proportion of patients in the VISION and CREED study also reported fasting outside of Ramadan. This data was not reported in the EPIDIAR study.

Although mean body weight and mean BMI increased over time, this may be attributed to the different populations analysed, the obesity epidemic, or chance alone. The duration of Type 2 diabetes mellitus increased over time, however, this may be due to different study design. All patients enrolling in the VISION study had to be receiving insulin injection therapy for the first time, while enrolment was less restrictive for the other 2 studies. Baseline HbA1c was higher for patients in the VISION study compared to the CREED study. This difference in HbA1c may also be due to the different study designs, where patients enrolling in the VISION study had to be receiving insulin injection therapy for the first time at the baseline visit, and may be requiring treatment intensification. Baseline HbA1c was not reported in the EPIDIAR study [2].

In terms of medical history, the most frequent diabetes complications across all studies were hypertension, dyslipidemia and diabetic neuropathy. A decrease over-time in the proportion of patients who fasted during Ramadan with diabetic retinopathy, nephropathy and peripheral arterial disease was observed. For hypertension, diabetic neuropathy, dyslipidemia, and cardiovascular disease, a trend overtime was not noted. The change in prevalence of complications reported may be explained by changes in the management of patients with diabetes over the last 15 years, however, the inclusion of countries with differential access to newer medications and the different populations analysed must also be considered as a source of bias. While no data was collected in CREED, from EPIDIAR to VISION, there was a decrease in the proportion of patients without a formal education over time. In terms of patients receiving HCP advice, 62% of patients in the EPIDIAR study were given advice on fasting during Ramadan, increasing to 96% of patients in the CREED study, and 100% of 169 patients whose data was recorded in a diary in the VISION study. Although all patients in the VISION study were receiving insulin therapy for the first time, education during the first initiation of insulin did not usually include advice on fasting during Ramadan and was unlikely to have influenced the proportion of patients reporting receiving HCP advice. The increase in the proportion of patients receiving advice on fasting during Ramadan over time suggests that HCPs are following the guidelines on patient education. Education and pre-Ramadan assessment are essential for successful management of patients with diabetes during Ramadan [1,8].

Despite guidelines and education as guided by EPIDIAR and CREED, the main limitation of the VISION Ramadan substudy was the gap in fasting related data collection. In EPIDIAR and CREED, data was recorded within a month post-Ramadan, whereas in the VISION study, visits may have occurred up-to 6 months post-Ramadan. Unless observational studies are Ramadan focused, they may fail to fully record important Ramadan related data. There are also limitations of comparing 3 different studies in different patient

populations, different treatments, and different countries/regions.

In conclusion, the present study provides an update on the characteristics and Ramadan experience of patients with Type 2 diabetes mellitus who initiated insulin therapy and chose to fast during Ramadan. The proportion of patients receiving advice on fasting during Ramadan has increased over time. The majority of patients fasted for the full month of Ramadan, and around one-third of patients also fasted outside Ramadan.

There is still a need to explore patient's experience during fasting, and to identify and address methods to better help manage those patients. Caregivers must recognise the unique needs of patients with Type 2 diabetes mellitus when choosing appropriate treatment and management strategies. Education and pre-Ramadan assessment are essential components for successful management of patients with Type 2 diabetes mellitus during Ramadan. Patients classified as high or very high risk need close medical supervision and focused Ramadan-specific education if they insist on fasting [1,8].

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Conflict of interest

AJ is a former employee of Eli Lilly and Company. IB, TT, and ES are employees and share-holders of Eli Lilly and company. VR is an employee of Eli Lilly and company. KT, WMIWM and SHAK have no conflict of interests to declare.

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