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Diabetes Research
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Diabetic hypoglycaemia during Ramadan fasting: A trans-national observational real-world study



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ARTICLE INFO

Article history:

Received 9 January 2019

Accepted 20 January 2019

Available online 14 February 2019

Keywords:

Diabetes

Fasting

Hypoglycaemia

Insulin therapy

Ramadan

ABSTRACT

Objectives: To describe the risk of hypoglycaemia during Ramadan and determine its risk factors, and the impact of hypoglycaemia on patients' behaviour.

Methods: A cross-sectional multi-country observational study, with data captured within 6 weeks after Ramadan 2015. Patients' and disease characteristics and its management, the risk of hypoglycaemia and patients' response to hypoglycaemia were recorded.

Results: A cohort of 1759 patients; majority with type 2 diabetes mellitus from North Africa, Arabian Gulf, Saudi Arabia, and the Indian subcontinent. Hypoglycaemia was reported by 290 patients (16.8%); particularly affecting type 1 diabetes patients and in insulin-treated patients in general. Age was significantly younger in the hypoglycaemia group ($P < 0.001$). The commonest responses were reducing the dose or frequency of medications (42%), attending primary care providers (24.5%) or increasing monitoring (20.7%). Fasting was interrupted by 67% only of those who experienced hypoglycaemia and recourse to emergency services was pursued by less than a quarter of patients with hypoglycaemia. The country-wise analysis of the rates of hypoglycaemia was greatest in Egypt (51.3%) and lowest in Pakistan (3.5%).

Conclusions: Hypoglycaemia is a significant complication of fasting during Ramadan. It may be predicted by type of diabetes, and use of insulin. Patients' responses are varied and call for more formal pre-Ramadan education.

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<https://doi.org/10.1016/j.diabres.2019.01.039>

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1. Introduction

Millions of adult Muslims fast from dawn until dusk during the annual Islamic holy month of Ramadan [1,2]. During the fast, Muslims abstain from food and drink and oral medications [1,2]. Although sick people are in principle exempted from fasting, several studies demonstrated that patient with chronic conditions, such as diabetes, may not recognise themselves as ill and thus insist on observing the fast taking the risk of complications [3,4]. Regarding diabetes, daytime hypoglycaemia remains the most prominent event during Ramadan fasting feared by both patients and physicians [5,6]. Ramadan and diabetes guidelines and widely-accepted expert opinion recommend that most patients with diabetes should not fast during Ramadan if they are at increased risk of hypoglycaemia [7–9]. However, patients may decide to observe the fasting against medical advice [10]. Hypoglycaemia is a core defining factor in the definition of risk stratification of patients by all the current guidelines [7–9], and this opinion is supported by authoritative religious scholars [2,9].

However, in two epidemiologic studies, the majority of patients with type 2 diabetes (T2DM) fasted for at least 15 days during Ramadan, with an observed increase in the incidence of severe hypoglycaemia relative to the preceding months [3,4]. Therefore, the question of risk of hypoglycaemia during fasting and its potential attribution to various classes of anti-diabetic medications is unsettled and is debated actively [11]. In particular, the potential advantages of the newer oral and injectable antidiabetic agents with their inherent low hypoglycaemic risk are of great interest [12,13]. Notwithstanding, evaluating the hypoglycaemic potential of all agents and response of patients to hypoglycaemia is essential as the newer agents and access to monitoring are not uniformly available globally, nor readily supported by all funding agents and societies [14].

Risk of hypoglycaemia may vary according to many circumstances. During Ramadan, it may reflect strictness, drive to fast, dietary and social changes, working hours and habitual exercise and the main lines of diabetes management in a given region. We have aimed to evaluate the risk of hypoglycaemia during Ramadan fasting in the real world in several countries. We wished specifically, firstly, to ascertain the risk and the determinants of reported hypoglycaemia in Muslim patients observing Ramadan fasting and secondly; to explore the impact of hypoglycaemia on patients and their response thereto.

2. Patients and methods

2.1. Settings

The study was conducted at 7 secondary diabetes care centres in 5 countries. In Asia, Baqia Center for Diabetes and Metabolism; Pakistan and KGN-Diabetes & Endocrinology Centre, Mumbai, India.

In the Arabian Gulf, Sheikh Khalifa Medical City, Abu Dhabi, Tawam Hospital, Al Ain, Dubai Hospital, Dubai, UAE, Al Ameri Hospital, Kuwait and Dammam Diabetes Center, Dammam, Saudi Arabia. Also in North Africa, the Diabetes Clinic, Alexandria University, Alexandria, Egypt.

2.2. Design

This was a multicenter cross-sectional survey of patients seen in ordinary diabetes clinic appointments within a short period after Ramadan fasting compatible with a reasonable recall. Patients were recruited by convenience sampling; all consecutive patients seen by participating physicians during the study period were included if agreeable. Data collection spanned over two months period from the end of Ramadan of 2015. Data captured included: demographics, diabetes' type, duration, and treatment. The frequency of comorbidities and risk factors, fasting observation status, the occurrence of hypoglycemia and its impact on fasting practices and diabetes management/monitoring behaviour.

2.3. Survey questions

The survey dataset was developed *de novo* by SAB and MMH to cover the study objectives. The data set included information on the investigator and subject, Ramadan fasting practices, patients' hypoglycaemia questionnaire (occurrence, risk factors, response), diabetes questionnaire (type and duration of diabetes, HbA1c, anti-diabetic therapy (class, regimen), and also diabetic complications and comorbidities. In summary, we captured demographic data, characteristics of diabetes and its management, ability to fast. The occurrence of hypoglycaemia, its impact on the patients' wellbeing, and the responses of patients to the hypoglycaemic events including changes in treatment, fasting, monitoring and recourse to emergency services were captured in detail. As a real-world study, definitions of various events including hypoglycaemia were based on the routine clinical practice as deemed appropriate by patients and physicians. No unified definitions were imposed on the investigators. The data collection sheet is shown in [Appendix A](#).

2.4. Data analysis

The investigator entered their patients/data directly on an online database "survey monkey software" except for Pakistan's site who provided their data tabulated in a spreadsheet. Data from the survey monkey soft were exported to a Spreadsheet (Excel, MS Office) and this was amalgamated with the data from Pakistan. The single spreadsheet was analysed anonymously. Data are presented using descriptive statistics with a mean \pm standard deviation for continuous variables and absolute and relative frequency for categorical variables. Differences between groups were sought using Chi-square and $P < 0.05$ was accepted as statistically significant.

3. Results

3.1. Characteristics of patients

Data on 1795 patients were available for analysis. They were 1002 males, and 793 females. Majority (1668) had T2DM, and a smaller proportion (127) had type 1 diabetes (T1DM). The mean age was for the whole group 51.3 ± 11.5 years. Duration of diabetes was 8.4 ± 6.8 years being <5 years (793), 5–10 years (538), 11–15 years (258), 16–20 years (142) and >20 years (128). Baseline HbA1c was $8.2 \pm 1.4\%$; serum HbA1c <7% (348), 7.1–8.0% (577), 8.1–9.0% (521), >9.0% (439). The demographic, clinical and metabolic profiles of all the patients' population as a whole are summarised in Table 1. These data for patients who reported hypoglycaemia and those who did not suffer hypoglycaemia are shown separately. Country-wise description is shown in Table 2. It is noteworthy that patients from India were mostly T2DM and those from Pakistan and India were younger age than the other countries. Also, the distribution between T1DM and T2DM were not similar between the different countries. Oral antidiabetic medications were used by 540 patients. Insulin only was used by 149 patients and the combination of both used by 277 patients. But some data points were missing in some patients for no obvious reason (Table 3). The latest available peri-Ramadan HbA1c values were significantly different between the five subgroups with KSA, Egypt and Pakistan being greater than India and the Gulf.

3.2. Intentions and abilities to fast

Majority of the patients seen during reported their intention to fast (1800, 96%). However, 1079 managed to fast full month; and 421, 146 and 149 could fast 21–28, days 11–20 days and 1–10 days respectively. Some of the none fasting days is related

to the religious regulation for women not to fast during the menstrual cycle. These data were not consistently collected and were not taken into consideration in the analysis.

3.3. Rates of hypoglycaemia during fasting

290 (16.2%) patients reported hypoglycaemia while 1505 (84.8%) patients did not recall experiencing any hypoglycaemia. Age was significantly younger in the hypoglycaemia group ($P < 0.001$). There was no impact of gender on the risk of hypoglycaemia (Table 1). Duration of diabetes was significantly longer in those who sustained hypoglycaemia, and there was a higher risk of hypoglycaemia in patients with T1DM than those with T2DM (Table 1). There was no difference in the latest HbA1c between the hypoglycaemia and non-hypoglycaemia groups (Table 1). The macro and microvascular complications and risk factors were more prevalent in patients with hypoglycaemia than in those without hypoglycaemia (Table 1). The rates of hypoglycaemia in the six countries by age, gender, type of diabetes and duration of diabetes are summarised in Table 2. Rates of hypoglycaemia were highest in Egypt (51.3%) and lowest in Pakistan (3.5%). However, formal statistical comparison between countries was deemed inappropriate as there were differences in type of diabetes and type of treatment across the countries.

3.4. Hypoglycaemia and medications

The relationship of hypoglycaemia to the classes, regimens and combinations of drugs used during Ramadan fasting are presented in Table 3. Hypoglycaemia was specifically associated sulphonylureas ($P < 0.001$) and all forms of insulin ($P < 0.001$) with the exception of basal insulin which showed a non-significant trend ($p = 0.089$). The risk associated with SGLT2 inhibitors, Acarbose, Glinides, GLP-1 RA's were not sta-

Table 1 – Baseline demographic and clinical characteristics and chronic complications and risk factors in total and by the occurrence of hypoglycaemia.

Variables	All patients	Patients by hypoglycaemia		
		Hypoglycaemia	No hypoglycaemia	P-value
Numbers	1795	290	1505	–
Sex: Male/Females	1002/ 793	170/120	832/673	NS
Type of Diabetes (Number (%))				
Type 1	127	68 (53.5%)	59(43.5%)	<0.001
Type 2	1668	222 (13.3%)	1446(86.7%)	
Age (years)	51.3 ± 11.5	48.5 ± 16.9	51.9 ± 10.1	<0.001
Type 1	25.5 ± 9.3	25.4 ± 9.8	25.4 ± 8.8	NS
Type 2	53.3 ± 9.0	55.9 ± 11.2	52.9 ± 8.5	<0.0001
Duration of diabetes (years)	8.4 ± 6.8	12.1 ± 7.9	7.7 ± 6.3	<0.001
Type 1	12.9 ± 6.5	12.9 ± 7.0	13.0 ± 6.0	NS
Type 2	8.1 ± 7.0	12.0 ± 8.2	7.5 ± 6.5	<0.0001
HbA1c (%)				
Type 1	8.8 ± 1.6	8.7 ± 1.6	8.9 ± 1.6	NS
Type 2	8.1 ± 1.4	8.1 ± 1.6	8.1 ± 1.4	NS
Chronic kidney disease	135	78/135 (57.8)	57/135(42.2%)	<0.0001

Data presented as Mean \pm S.D or n (%); Chi-square test or t-test was used for p-values; P-value < 0.05 was considered statistically significant.

Table 2 – Characteristics of study participants by country, age, gender, duration, type and control of diabetes and the rates of occurrence of hypoglycaemia.

Country/region	Gender		Age (years)	Type, duration and control of diabetes				Hypoglycaemia	
	M	F		T1DM	T2DM	Duration (years)	HbA1c	Yes	No
Egypt	78	72	52.1 ± 13.1	14	136	11.3 ± 8.1	8.4 ± 1.8	77(51.3%)	73(48.7%)
India	198	102	52.5 ± 10.0	1	299	6.4 ± 4.4	7.8 ± 1.5	42(14.0%)	258(86.0%)
KSA	111	75	50.9 ± 14.4	27	159	13.1 ± 8.7	9.2 ± 2.3	43(23.1%)	143(76.9%)
Pakistan	409	391	49.9 ± 8.2	35	765	5.8 ± 3.9	8.3 ± 0.9	28 (3.5%)	772(96.5%)
Gulf	206	153	53.5 ± 16.3	50	309	13.0 ± 9.1	7.7 ± 1.7	100(27.9%)	25(72.1%)

Data presented as Mean ± S.D or n (%).

KSA: Kingdom of Saudi Arabia; Gulf (includes United Arab Emirates and Kuwait).

Table 3 – Frequency of hypoglycaemia by individual medications, classes, regimens and combinations used during Ramadan fasting. Data are shown as absolute and relative frequencies (not mutually exclusive).

Medication and regimens	All patients	By hypoglycaemia		
		Yes	No	P-value
I. Non-insulin medications/classes (could be part of any combinations)				
Metformin	724	143	581	<0.001
Sulphonylureas	475	102	373	<0.001
DPP-IV inhibitors	329	58	271	0.424
Pioglitazone	38	15	23	<0.001
SGLT2 inhibitors	37	8	29	0.363
Others (Acarbose, Glinides GLP-1 RA)	67	5	62	–
II. Insulin regimens (with or without other agents)				
Basal insulin	109	23	81	0.089
Basal plus insulin	39	15	24	<0.001
Basal-bolus insulin	111	51	60	<0.001
Premixed insulin BID or TID	153	62	91	<0.001
Insulin pump therapy	29	22	7	<0.001
III. Therapy regimens and combinations				
OAD drugs (only)	540	80	460	0.312
Insulin only (any)	149	92	57	<0.001
Insulin with any OAD drug	277	84	193	<0.001

Data presented as n (%); Z-score for two population proportion test was used for p-values; P-value < 0.05 was considered statistically significant. OAD: oral antidiabetic drugs. No statistical analysis was made for small samples.

tistically evaluated as the numbers were too small. When combinations were considered, the inclusion of insulin was associated with higher risk of hypoglycaemia (Table 3).

3.5. Responses to hypoglycaemia

The replies to the questions related to the impact of the occurrence of hypoglycaemia on patients' behaviour are presented in Fig. 1. By far the most frequent response was a reduction of the dose or frequency of medications (42%) followed by attending their primary care providers (24.5%) or increased the frequency of monitoring (20.7%). However, there is a concern that nearly one in five did nothing but 11% omitted the medications and continued fasting (Fig. 1A). The breaking of the fast was reported by 67% of those with hypoglycaemia (Fig. 1B). Recourse to emergency services was only pursued by less than a quarter of 235 patients with hypoglycaemia (15% attended emergency departments, and 7% got admitted to hospital). (Fig. 1C). Other specific actions including a delay of the *suhour*, change of

insulin pump setting, reduction or stopping exercise, contacting a pharmacist, and increasing the sugar intake at dawn meal to intentionally become hyperglycaemic to avoid further hypoglycaemic attacks during the fast. There was a direct relationship between the occurrence of hypoglycaemia and the number of days fasted in those who break the fasting (Chi-square test; p-value < 0.05) (Fig. 2).

4. Discussion

Hypoglycaemia was identified as a core definer for the various risk stratification systems [6–9]. The present study enriched the real-world data on the risk of hypoglycaemia during Ramadan fasting in people with diabetes thus lending support to the previously proposed risk scales. The specific contribution was the identification of the size of the problem, predictors of hypoglycaemia, and the patients' responses to it. The quest to observe the fast was very high similar to previous studies [3], and reemphasises the need for studies that may help enable safer fasting. The overall incidence of hypo-

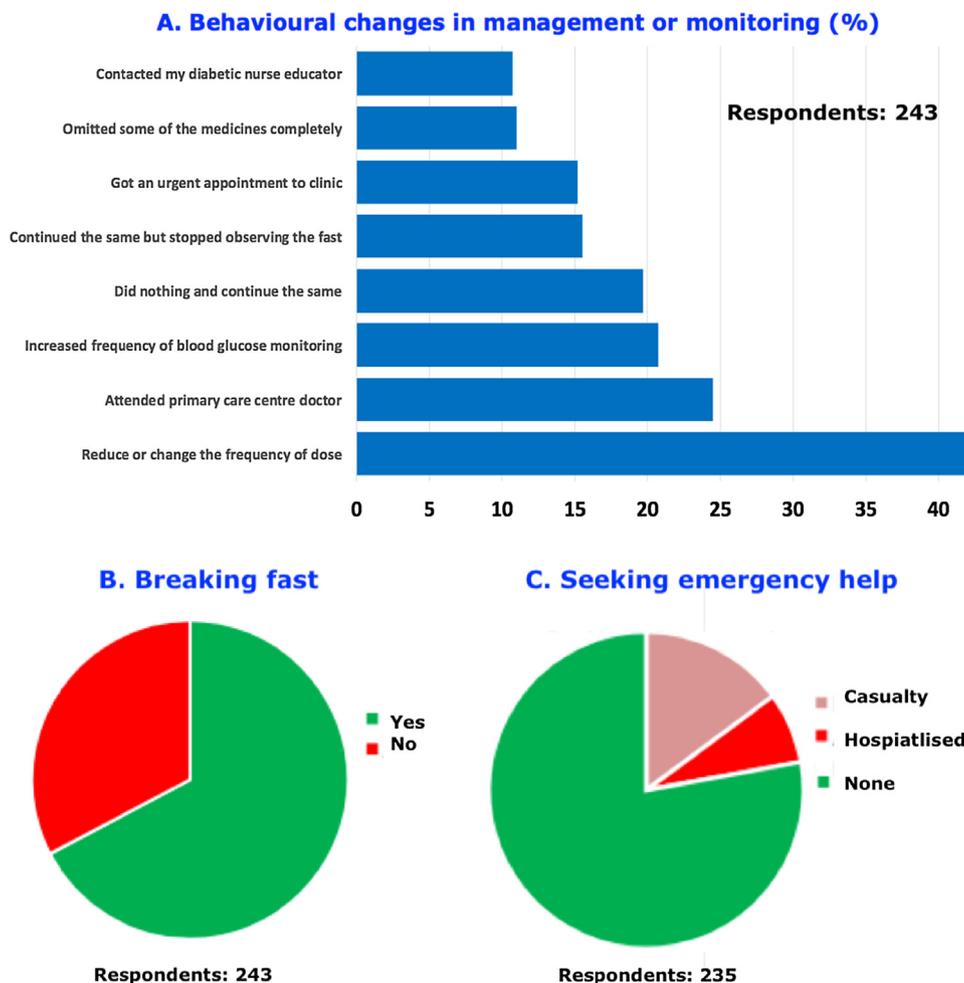


Fig. 1 – Patients’ responses to hypoglycaemia during Ramadan fasting: A. Behavioural changes in management and monitoring B. The need to break the fast, and C. The recourse to emergency services (i.e. attendance at emergency departments and emergency admission).

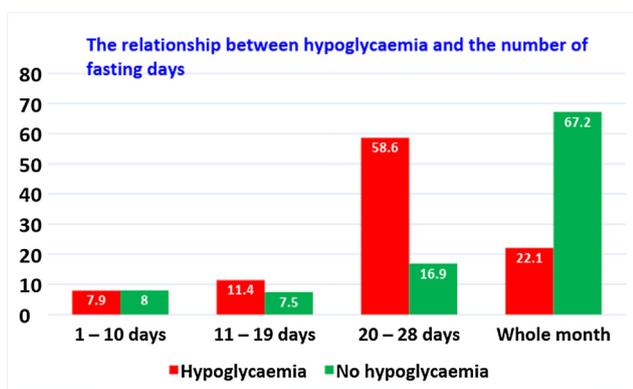


Fig. 2 – Ability to fast numbers of days in relation to occurrence of hypoglycaemia. Chi-square test was used; p-value <0.001.

glycaemia, during Ramadan, for the entire cohort was relatively higher than previous studies 16.8% which might reflect that data was exclusively collected from specialised centres rather than in primary care settings since intensive insulin regimens, guest for tight glycaemic control and frequency of

complications may be greater in the specialist care than in primary care [15]. Hypoglycaemia was predictably greater in T1DM patients and also in those treated with insulin therapy in general either on its own or in combination with other agents. This is true for Ramadan as it for outside of Ramadan. The risk of hypoglycaemia in basal insulin only-treated patients did not reach statistical significance as the effect of insulin tends to wear out as the fasting time continue. Also, the difference in risk of hypoglycaemia in T2DM under different insulin regimens has been shown previously [16]. These differences are similar qualitatively to previous studies [4]. Concerning, the impact of the occurrence of hypoglycaemia on patients’ behaviour, by far the most frequent response was a reduction of the dose or its frequency (42%). One-quarter of these patients attended their primary care providers, and one fifth increased the rate of monitoring. One in five made no changes and one in ten merely omitted their medications and continued fasting. The appropriateness of these actions is difficult to assess from the survey as we do not know if these measures helped to reduce the frequency of hypoglycaemia or not and whether they had any detrimental effect on overall glycaemic control or not. Of concern, the fast was interrupted by one-third of those with

hypoglycaemia whereas the rest continued fasting despite hypoglycaemia. This action is clearly against the standard advice included in all the pre-Ramadan education programs whereby patients are recommended invariably to discontinue the fast in case of any degree hypoglycaemia [20,21] since the rate of worsening of hypoglycaemia cannot be predicted confidently if fasting is continued. This behaviour was observed in other studies [4]. Findings of the present and previous studies call for universal access to pre-Ramadan educational programs [7–10].

Recourse to emergency services was only pursued by less than a quarter of patients with hypoglycaemia. Studies on utilisation of emergency resources have focused on the late surge and have not suggested a remarkable change in a majority of clinical conditions seen [17].

The study was designed as a real-world observational study with no manipulation of patients' or practitioners' behaviour to ascertain the impact of the Ramadan fasting rather than the use of specific diets, medications, or educational manoeuvres since the study was cross-sectional study assessing patients' recollection of their recent experience. However, capturing data within weeks after Ramadan allowed assessment of the hypoglycaemia risk in the whole month while events are still within the living memory [4,18]. Furthermore, hypoglycaemia is a memorable event for all patients with diabetes particularly during Ramadan as the person needs to re-compensate for days where they didn't fast. The study involved patients from 3 different regions, North Africa, The Gulf, and the Indian subcontinent but we accept differences in the clinical and therapeutic profiles may be different. However, our focus on the occurrence of hypoglycaemia itself in the whole study rather than its interregional difference which was not predefined as a study objective. The difference in hypoglycaemic risks between these regions have been demonstrated in a previous study [19]. Patients' responses varied with reduction of dose or frequency being the most consistent. The GAPP2 study showed similar but not identical trends affecting the medications and utilisation of services in responses to self-treated hypoglycaemia on basal insulin therapy [20]. The individual exposure to structured education was not captured in the present study; however, several studies proved the role of pre-Ramadan education of whatever model [21,22].

The study has a couple of noteworthy limitations. Data were captured by the recollection of events within living memory of a few weeks rather than diary-based documentations. However, hypoglycaemia and breaking of the fast are significant medical and social events that cannot be forgotten readily [18,19]. The study was intended to document the impact on the patient behaviour and response to the hypoglycaemic event. Although the use of several sites may be viewed positively to reflect practices in more extensive geographical regions, this may introduce systematic errors and confounders based on the differences of the social backgrounds and the different patterns of medical practice and prescribing habits between areas. Also, the final sample was not homogeneous on several counts as discussed above. We have not documented the receipt of pre-Ramadan education; some of the responses of individual patients may suggest that many did not receive any education which is a reflection of the real

world. Also calculating the fasting days did not take account of women in the reproductive age. It is also arguably, that reporting "any hypoglycaemia" may have contributed to over-estimating hypoglycaemia in general in comparison with other studies.

In conclusion, hypoglycaemia in Ramadan in patients of this hospital clinic-based study is relatively increased. T1DM and the use of insulin therapy could predict the increased risk of hypoglycaemia during fasting. Patients' behaviours in response to hypoglycaemia were widely different. Intercountry differences are likely reflective of varying management strategies. Similar studies of low cost, real-world nature are needed continuously to follow the changes in medication usage, and provision of educational activities need to be documented in more details. Focus on hypoglycaemia in Ramadan fasting during Ramadan focused education is mandatory.

Acknowledgement

The authors would like to thank their supporting staff at all the clinical sites of the study who have helped in patient identification or data collection to any extent. They also record their appreciation to patients who agreed to be included.

Authors' contribution

SAB and MMH made equal contributions. SAB and MMH conceived the idea of the study as a quality assurance exercise and developed the data collection instrument. SAB managed the central data collection through the central software, performed the initial data analysis and drafted the manuscript. All authors contributed to data collection at their own centres' revised the data analysis and critically revised the draft manuscript. All authors approved the final revised manuscript.

Funding

This study received no funding from any source, public, private or pharmaceutical.

Conflicts of interests

None of the authors declared any conflicts of interests related to this study.

Compliance with ethical principles

Despite recognising that there is no risk to human subjects, formal ethical approval was granted by the SKMC Institutional Review Board (Abu Dhabi, UAE) where the survey was managed as by local convention. Verbal consent was obtained from patients prior to entering their data. All data were collected, stored and analysed anonymously.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2019.01.039>.

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