A Population-Based Study of Diabetes and Its Characteristics During the Fasting Month of Ramadan in 13 Countries

Results of the Epidemiology of Diabetes and Ramadan 1422/2001 (EPIDIAR) study

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OBJECTIVE — The aim of this study was to assess the characteristics and care of patients with diabetes in countries with a sizable Muslim population and to study diabetes features during Ramadan and the effect of fasting.

RESEARCH DESIGN AND METHODS — This was a population-based, retrospective, transversal survey conducted in 13 countries. A total of 12,914 patients with diabetes were recruited using a stratified sampling method, and 12,243 were considered for the analysis.

RESULTS — Investigators recruited 1,070 (8.7%) patients with type 1 diabetes and 11,173 (91.3%) patients with type 2 diabetes. During Ramadan, 42.8% of patients with type 1 diabetes and 78.7% with type 2 diabetes fasted for at least 15 days. Less than 50% of the whole population changed their treatment dose (approximately one-fourth of patients treated with oral antidiabetic drugs [OADs] and one-third of patients using insulin). Severe hypoglycemic episodes were significantly more frequent during Ramadan compared with other months (type 1 diabetes, 0.14 vs. 0.03 episode/month, $P = 0.0174$; type 2 diabetes, 0.03 vs. 0.004 episode/month, $P < 0.0001$). Severe hypoglycemia was more frequent in subjects who changed their dose of OADs or insulin or modified their level of physical activity.

CONCLUSIONS — The large proportion of both type 1 and type 2 diabetic subjects who fast during Ramadan represent a challenge to their physicians. There is a need to provide more intensive education before fasting, to disseminate guidelines, and to propose further studies assessing the impact of fasting on morbidity and mortality.

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The prevalence of diabetes in several countries with large Muslim populations appears to be similar to the rates observed in western countries and increasing by 10% per year as a result of urbanization and socioeconomic development (1). There are >1 billion Muslims in the world, and the majority of them observe an absolute fast (no food or water) between dawn and sunset 1 lunar month a year (the Holy Month of Ramadan). Indeed, fasting is one of the five pillars of Islam. However, when fasting may significantly affect the health of the faster or when a subject is sick, Islam exempts that person from fasting. However, a significant number of patients persist in fasting against the advice of their doctors and the permission of religious authorities.

Although several large epidemiological studies have been performed in Asia (2–4), the Middle East (5,6), and in the Maghreb countries (7,8), there is still a lack of information about the standard management of diabetes in the Muslim world. However, these previous studies have not specifically addressed diabetes management during Ramadan, and there are no epidemiological data available on the proportion of diabetic patients who fast during Ramadan.

Some studies have looked at the biochemical changes occurring during Ramadan fasting both in normoglycemic subjects (9–15) and in subjects with diabetes (16–25). Most of these have showed little change in glycemic control, although blood lipid levels and body weight have sometimes been shown to be reduced (19,22–24). Moreover, it seems clear that fasting blood glucose levels can be stabilized with good dietary control (20–22,24). Certain oral antidiabetic drugs (OAD), including glibenclamide and repaglinide, may be used safely and effectively during Ramadan in type 2 diabetes (8,22), and certain insulin derivatives may be of interest for subjects with type 1 diabetes who insist on fasting during Ramadan (26).

An International Consensus Meeting was held in Morocco in 1995 (27) to establish guidelines pertaining to definitions of patient groups who should be

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Abbreviations: OAD, oral antidiabetic drug.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

exempted from fasting, as well as recommendations on medication regimens and monitoring of diabetes before, during, and after Ramadan. Diagnostic criteria for permitting fasting with acceptable risk were identified, including patients with type 2 diabetes treated with biguanides or sulfonylureas who were stable and did not have any complicating progressive comorbid pathology. On the other hand, patients with type 1 diabetes, with unstable disease, with comorbid degenerative disease, who are pregnant, and the elderly should be exempted from fasting. Monitoring was recommended before, during, and after Ramadan, and education programs for patients were proposed.

It is not known, however, to what extent these guidelines are followed in practice. In addition, lifestyle changes, the frequency of complications in patients with diabetes who fast during Ramadan, and changes in treatment regimen during Ramadan remain largely unknown. To provide data on diabetic patients and their management during Ramadan, we have conducted a large population-based, multicountry epidemiological study of diabetes in 13 countries with Muslim populations.

The objectives of this study were twofold. The first objective was to determine the characteristics of patients with diabetes and to assess their care in countries with a sizable Muslim population. The second objective was to study diabetes presentation during the Holy Month of Ramadan and the potential effects of fasting on patient well-being and on diabetes management.

RESEARCH DESIGN AND METHODS

— Thirteen countries with a Muslim population participated in the study: Algeria, Bangladesh, Egypt, India, Indonesia, Jordan, Lebanon, Malaysia, Morocco, Pakistan, Saudi Arabia, Tunisia, and Turkey.

In each country, a randomly selected stratified sample of general practitioners, endocrinologists (diabetologists), and internists involved in the care of Muslim patients with diabetes was enrolled. The proportion of general practitioners, endocrinologists, and internists was chosen to reflect the relative weight of each area of medical specialization involved in diabetes care. Each selected practitioner was invited to participate in the study. If the targeted physician declined, the next practitioner on the random list from the same specialty was invited to participate. This process was continued until 100 practitioners were obtained in each country. This sample size was calculated to produce country-specific results with an acceptable degree of accuracy of ~50% estimate (CI 47–53%).

A cluster sampling method was used to select the study population, which comprised 12,914 volunteer and eligible patients. Inclusions began immediately after the end of the month of Ramadan of Muslim year 1422 (i.e., 2001) until January 2002. During this period, each investigator was expected to enroll the first 10 eligible patients who had come for consultation (regardless of the purpose of their visits). The criteria of inclusion were a diagnosis of type 1 or type 2 diabetes and ability to complete a brief questionnaire about their disease and health care. Newly diagnosed patients (<3 months) and hospitalized patients were excluded from the study.

Data collection

A standardized questionnaire-based interview was conducted by the investigator who enrolled the study subjects to collect detailed information on a one-to-one basis during face-to-face interviews. Data collected included *1*) sociodemographic data, diabetes type, duration of the disease, complications, and comorbidities; *2*) current treatment, frequency, and type of medical follow-up (self-monitoring and monitoring of glycemia); *3*) physical activity, food/fluid intake, sleep patterns, and body weight; and *4*) consequences of the Ramadan period with regards to change in lifestyle, change in treatment, and change in frequency of hypo/hyperglycemia episodes. Severe hypoglycemia was defined as hypoglycemia leading to hospitalization. The methodology of the study and recommendations on how to conduct the interviews and complete the questionnaires were presented to each investigator during briefing meetings by representatives of the study sponsor. An identical questionnaire was used in each country and was translated into the local language.

Data were first captured locally in each National Study Center using a computerized data-capture mask. All data were centralized in the International Analysis Center based in Antony (France) through a global Intranet system. All questionnaires completed by investigators were also centralized in the International Analysis Center, and a second complete data capture was performed and matched with the first one. Discrepancies were edited and resolved at both national and international levels. Computer-assisted consistency checks were performed. Dubious questions and results were presented to the EPIDIAR (Epidemiology of Diabetes and Ramadan 1422/2001) Study Group for comments.

Study population

Among the 12,914 patients initially enrolled in the study, 671 (5.2%) patients with an original reported diagnosis of type 1 diabetes were excluded from the analyses. Their diagnosis was considered doubtful because they were either not treated or treated with OAD only or they had been diagnosed after 40 years of age. Supporting this assumption, we observed only minor differences in age and sex distribution between this "unclassifiable" group of patients and the group of subjects with type 2 diabetes.

Statistical analyses

Two-tailed tests were used throughout, and a probability level of 0.05 was considered significant. All variables were analyzed overall and by country. Continuous variables were described by the frequency distribution, mean, median, standard deviation, and extreme values. Discontinuous (categorical [nominal/ordinal]) variables were described by the documented frequency and frequencies of each modality. For qualitative data, group comparisons were performed using the χ^2 test, otherwise Fisher's exact test was performed. For quantitative data, analysis of variance was performed after having checked for normality and homoscedasticity of the residues, otherwise nonparametric tests were used. All statistical analyses were performed using SAS software package version 8.0 for Windows (SAS Institute, Cary, NC).

RESULTS

General characteristics of the population

Data were analyzed from 12,243 subjects in 13 countries. Patient numbers ranged from 757 in Morocco to 1,357 in Bang-

ladesh. Of these, 1,070 (8.7%) corresponded to type 1 diabetes and 11,173 (91.3%) to type 2 diabetes. The proportion of type 1 and type 2 diabetes was similar in most countries (6.2–15.6%), although in the southern Asian countries (Bangladesh, India, Indonesia, and Malaysia), the proportion of type 1 patients was low (1.1–4.4%). On the other hand, the proportion of type 1 patients in Saudi Arabia was particularly high (27.7%).

The overall demographic and clinical features of the survey population are shown in Table 1. This population was relatively young (age 31 and 54 years for type 1 and type 2 diabetes, respectively) with a short duration of diabetes (10 and 7.6 years, respectively). Mean BMI was 24 kg/m^2 in type 1 and 27,2 kg/m^2 in type 2.

The overall frequency of diabetes complications and comorbidities was relatively high. The three most frequently reported complications were neuropathy, retinopathy, and nephropathy (Table 1). Diabetes-related foot ulcers were observed in <10% of subjects. Hypertension and dyslipidemia were more frequent in type 2 diabetes than in type 1 diabetes (Table 1). Important discrepancies between countries in the frequency of complications were noted; for example, in type 1 diabetes, the frequency of reported neuropathy varied from 7.6% in Saudi Arabia to 70.0% in Indonesia. In type 2 diabetes, the lowest and highest frequencies were 10.8% in Bangladesh and 42.1% in Egypt.

Table 1—*Demographic and clinical features of the survey population*

	Type 1 diabetes	Type 2 diabetes
n	1,070	11,173
Sex (%)		
Men	50.0	49.0
Women	50.0	51.0
Age (years)	31.0 ± 12.7	54.0 ± 11.0
Duration of diabetes (years)		
Time since diagnosis	10 ± 7.6	7.6 ± 5.8
Age at diagnosis	22 ± 9.5	47 ± 10.6
Height (cm)	163.1 ± 11.3	162.9 ± 9.3
Weight (kg)	64.1 ± 15.4	72.4 ± 14.7
BMI (kg/m^2)	24.0 ± 4.8	27.2 ± 4.9
Smoking (%)		
Current smokers	17.0	20.0
Nonsmokers	83.0	80.0
Residential location (%)		
Urban	79.0	80.0
Rural	21.0	20.0
Education level (%)		
No formal or primary education	30.0	51.0
Secondary or university level/higher education	70.0	49.0
Occupation (%)		
Manual worker	46.0	53.0
Office employee	54.0	47.0
Daily physical activity (%)		
Sedentary or light activity	38.0	52.0
Moderate activity	52.0	42.0
Heavy activity	10.0	6.0
Vigorous activity	0.0	1.0
Diabetes complication		
Neuropathy	256 (23.9)	3,101 (27.8)
Retinopathy	231 (21.6)	2,197 (19.7)
Nephropathy	152 (14.2)	1,354 (12.1)
Coronary artery disease	64 (6.0)	1,632 (14.6)
Peripheral arterial disease	84 (7.9)	1,117 (10.0)
Cerebrovascular disease	16 (1.5)	467 (4.2)
Foot ulcer	73 (6.8)	571 (5.1)
Amputation of lower limb	17 (1.6)	133 (1.2)
Comorbidity		
Hypertension	180 (16.8)	5,457 (48.8)
Dyslipidemia	151 (14.1)	3,633 (32.5)

Data are means ± SD or *n* (%), unless otherwise indicated.

Diabetes management

In this mainly urban population (80%), we observed that 10.3% of patients with type 1 diabetes and 26.2% of patients with type 2 diabetes were not followed by a specialist, the average number of visits per year to a physician was 9.6 and 8.3, respectively, for type 1 and type 2 diabetes. Moreover, 76% patients with type 1 diabetes and 69% of patients with type 2 diabetes were reported to obtain help in diabetes care from relatives. Recommendations and education, including counseling for blood glucose control and self-management of diabetes, were dispensed by physicians to 89% of patients with type 1 diabetes and to 80% of patients with type 2 diabetes. However, only 67% of patients with type 1 diabetes and 37% of patients with type 2 diabetes were monitoring blood glucose levels themselves.

In type 1 diabetes, 92.3% of the patients were treated with insulin alone and 7.7% with an association of insulin plus OAD, of whom 6.8% were taking a single OAD (3% sulfonylureas, 3% biguanide), whereas 78% of patients with type 1 diabetes receiving insulin had two injections per day. In type 2 diabetes, 78.4% of patients were treated with OAD alone (46.6% monotherapy; 28.8% bitherapy), 7.3% with a combination of insulin plus OAD (5.4% monotherapy; 1.6% bitherapy), and 9.4% with insulin alone. Among all patients with type 2 diabetes receiving insulin, 12% had two injections per day. A

proportion of 4.9% patients received no antidiabetes treatment.

Diabetes during Ramadan

As many as 42.8% of patients with type 1 diabetes and 78.7% of patients with type 2 diabetes reported fasting at least 15 days during Ramadan. Again, marked differences between countries were observed, particularly for type 1 diabetes, which varied from 9.4% in Morocco to 71.6% in Saudi Arabia. For type 2 diabetes, the proportion of subjects fasting for at least 15 days ranged from 57.8% in Turkey to 89.8% in Malaysia and Bangladesh. Patients with type 1 diabetes fasted for a shorter period than patients with type 2 diabetes; the average number of fasting days was 23 and 27 days for patients with type 1 and type 2 diabetes, respectively. Intercountry differences in mean fasting duration were minor, ranging from 18.1 day in Turkey to 25.6 days in Saudi Arabia for type 1 diabetes and from 23.9 days in Turkey to 28.5 days in Algeria for type 2 diabetes. Recommendations from their health care providers about fasting and diabetes during Ramadan were provided to 68% of the patients with type 1 diabetes and 62% of those with type 2 diabetes. Concerning food intake, 65% of patients with type 1 diabetes and 57% of patients with type 2 diabetes agreed that they might have a meal different from their family, and 73% of patients with type 1 diabetes and 55% with type 2 diabetes agreed that they could break fast during Ramadan.

Changes concerning lifestyle, weight, and treatment during Ramadan are shown in Table 2. Physical activity, sleep duration, food intake, fluid intake, and sugar intake were unchanged in approximately one-half of the study population. Weight was unchanged in 62.5% of the patients with type 1 diabetes and in 54.1% of the patients with type 2 diabetes. Insulin dose was continued unchanged in 64% of diabetic patients (both type 1 and type 2 diabetes), and the OAD doses were continued unchanged in 79 and 75% of patients with type 1 and type 2 diabetes, respectively.

During the year preceding Ramadan, 23% of patients with type 1 diabetes and 4% of patients with type 2 diabetes had experienced at least one episode of severe hypoglycemia requiring hospitalization. During Ramadan, these frequencies were 9 and 2%, respectively. During the year preceding Ramadan, 40% of patients with type 1 diabetes and 9% of patients with type 2 diabetes experienced at least one episode of severe hyperglycemia with/without ketoacidosis requiring hospitalization, compared with 13 and 4%, respectively, during Ramadan.

Frequencies of severe glycemic complications episodes occurring before and during Ramadan in both types of diabetes are shown in Table 3. Among the overall population, the number of severe hypoglycemic episodes per month and per patient was significantly higher during Ramadan than during the preceding year for patients with type 1 diabetes as well as for patients with type 2 diabetes. In addition, the number of severe hyperglycemia episodes with/without ketoacidosis per month showed a significant difference between Ramadan and the preceding year only for patients with type 2 diabetes. Among patients who fasted for at least 15 days, the frequency of both glycemic complications was slightly lower than in the overall population. For these patients, significant differences were reported in frequency of both complications per pa-

Table 2—*Changes in lifestyle, weight, and medication during Ramadan*

	Type 1 diabetes	Type 2 diabetes
n	1,070	11,173
Physical activity		
More	110 (10.8)	1,032 (9.4)
Less	358 (35.1)	4,028 (36.8)
Same	552 (54.1)	5,884 (53.8)
Sleeping duration		
More	250 (24.5)	1,772 (16.2)
Less	310 (30.4)	4,168 (38.2)
Same	459 (45.0)	4,984 (45.6)
Food intake		
More	206 (20.3)	2,025 (18.6)
Less	234 (23.1)	3,284 (30.1)
Same	574 (56.6)	5,594 (51.3)
Fluid intake		
More	228 (22.5)	2,210 (20.3)
Less	214 (21.1)	3,312 (30.4)
Same	573 (56.5)	5,356 (49.2)
Sugar intake		
More	237 (23.4)	2,452 (22.7)
Less	211 (20.8)	2,677 (24.7)
Same	565 (55.8)	5,688 (52.6)
Weight changes		
No change	562 (62.5)	5,286 (54.1)
Gain	161 (17.9)	1,861 (19.1)
Loss	176 (19.6)	2,628 (26.9)
Value of weight change (kg)		
Overall population	332 (0.12 ± 3.79)	4,367 (−0.25 ± 3.25)
Patients who fasted at least 1 day	235 (−0.51 ± 3.23)	4,152 (−0.32 ± 3.08)
Patients who reported weight gain	159 (+3.24 ± 2.71)	1,811 (+2.78 ± 2.49)
Patients who reported weight loss	173 (−2.74 ± 1.92)	2,556 (2.39 ± 1.61)
Insulin dose		
Increased	106 (10.7)	150 (8.2)
Decreased	237 (24.0)	452 (24.7)
Maintained	637 (64.5)	1,174 (64.1)
Stopped	8 (0.8)	55 (3.0)
OAD dose		
Increased	5 (5.3)	415 (4.4)
Decreased	14 (14.9)	1,779 (18.8)
Maintained	74 (78.7)	7,085 (74.8)
Stopped	1 (1.1)	197 (2.1)

Data are *n* (%) or *n* (means ± SD).

Table 3—*Number of severe glycemic complications per month*

	Type 1 diabetes			Type 2 diabetes		
	Before Ramadan	During Ramadan	*P*	Before Ramadan	During Ramadan	*P*
Overall population						
Severe hypoglycemia	0.03 ± 0.1	0.14 ± 0.6	0.0174	0.004 ± 0.02	0.03 ± 0.28	<0.0001
Severe hyperglycemia/ketoacidosis	0.05 ± 0.08	0.16 ± 0.51	0.1635	0.01 ± 0.05	0.05 ± 0.35	<0.0001
Patients who fasted ≥15 days						
Severe hypoglycemia	0.02 ± 0.05	0.12 ± 0.48	0.9896	0.003 ± 0.02	0.02 ± 0.22	0.0034
Severe hyperglycemia/ketoacidosis	0.05 ± 0.08	0.15 ± 0.51	0.6701	0.009 ± 0.04	0.04 ± 0.30	0.0015

Data are means ± SD.

tient per month between Ramadan and the preceding year for patients with type 2 diabetes but not type 1 diabetes (Table 3).

The impact of lifestyle and treatment changes on the incidence of glycemic complications during Ramadan was assessed for the entire population (subjects with type 1 and type 2 diabetes were pooled due to low numbers in some type 1 diabetic groups). Significant associations with the incidence of severe hypoglycemia were observed for a change in OAD dose (38.4% of subjects reporting severe hypoglycemia had changed their dose compared with 19.7% of those without severe hypoglycemia), a change in insulin dose (55.3 vs. 36.7%), and a change in the level of physical activity (64.7 vs. 45.5%). The proportion of subjects changing food or sugar intake was not significantly different in subjects with severe hypoglycemia and in those without. However, these last two variables were associated with the incidence of severe hyperglycemia with/without diabetic ketoacidosis ($P = 0.0012$ for change in food intake and $P < 0.0001$ for change in sugar intake).

CONCLUSIONS — This study reports a large, multicountry, population-based, epidemiological study in countries with Muslim populations. In this study, most of the physician investigators were located in urban areas and recruited a representative population of patients with diabetes.

The distribution of patients by diabetes type was similar to those observed in several parts of the world (28). Although some discrepancies were seen between countries, it appeared that type 2 diabetes was a little more common in women. This result was similar to those reported in some European countries (29) as well as in some Arab countries (30–32). It may be explained by a selection bias; the enrolled population was urban and had low or moderate physical activity. This was particularly true in women who had physical activity restricted to housework and who have no tradition of sport practices.

Despite the lower mean age of patients and the shorter duration of diabetes as compared with those currently observed in European countries (mean duration of diabetes of 9.3 years was reported) (33), an interesting finding concerned the frequencies of diabetes complications and comorbidities reported by practitioners, which were similar to those observed in western countries (34).

This study has provided prevalence estimates of fasting during Ramadan in the Muslim world among diabetic patients of 43% for type 1 diabetes and 86% for type 2 diabetes. In most cases, 50% of the whole population of diabetic patients (type 1 and type 2) did not change their lifestyle during Ramadan. However, when patients did change their lifestyle, the tendency was to decrease physical activity, sleep duration, and food, sugar, and fluid intake. Only approximately one in four patients treated with OADs and one in three patients treated with insulin changed their treatment dosage (up or down) during Ramadan.

The overall incidence of hypoglycemic events was rather low. This may be due to unawareness of symptoms by the patient, limited use of intensive therapies, insufficient monitoring, or restriction of the definition to hospitalization. However, we observed that severe hypoglycemia was more frequent during Ramadan than during the preceding year and associated with changes in treatment regimens and physical activity during Ramadan.

The study has a number of limitations. The subjects in the participating centers may not have been representative of all diabetic patients in certain countries. For example, the high proportion of subjects with type 1 diabetes in Saudi Arabia (27.7%) probably illustrates a selection bias. In countries such as Saudi Arabia where specialist diabetology centers contributed a large proportion of patients, the standard of care may represent the upper end of what is available in these countries. Another limitation is that data collection on items such as lifestyle and diet was from patient declaration, which may not be entirely reliable. In addition, diabetes complications and comorbidities were not systematically validated by case ascertainment from medical records. This may explain the large between-country differences observed in the frequency of comorbidities. On the other hand, severe hypoglycemia defined by hospitalization was a hard end point that could be confirmed from hospital records.

The large proportion of both type 1 and type 2 diabetic patients who fast during Ramadan represents a challenge to physicians to provide more intensive education before fasting and emphasizes the need for closer monitoring of blood glucose during fasting. Future studies are needed to more thoroughly address the impact of fasting on morbidity and mortality in high-risk patients. After completion of this study, we have prepared guidelines for the information and management of diabetic patients who wish to fast during Ramadan, which will be published shortly.

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