The Association between Health-Related Quality of Life and Ramadan Fasting in Diabetic Patients: a Survey Using a Structured D-39 Assessment Tool. A Sudanese Cohort

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A R T I C L E I N F O	A B S T R A C T
	Introduction: Most cases of chronic diseases result in physical, psychological, financial, and social burdens on the patients and the economy. The overall health-related quality of life of patients can be positively influenced by several variables including glycemic control, economic status, comorbidities, presence of complications, and the quality of medical, psychological, and social support. Studies examining the effects of fasting on diabetes during Ramadan fasting underline the biochemical changes without considering the psychosocial and financial implications. This study aimed to illuminate some of the challenges faced by both fasting and non-fasting diabetic patients during Ramadan. Further, we evaluated the quality of life of diabetes patients, explored the socio-demographic and disease-related variables, and estimated the percentage of diabetic patients who fasted during Ramadan. **Methods:** This was a community-based cross-sectional study conducted from August 2015 to October 2015. Diabetes 39 instrument was administered to 112 patients with diabetes in Khartoum to evaluate their health-related quality of life during Ramadan. **Results:** Fifty-four percent of study participants were female and 64.3% of them were aged between 40-60 years old. Sixty-two participants were able to fast (55.4%) and fasted for more than 15 days. Half of the participants had, at least, one comorbidity, among which hypertension was the most common. Approximately 59% of fasting patients had mild impairment in their health-related quality of life, whereas 60% of non-fasting participants had moderate impairment. Limited stamina, and fear of hypoglycemia were the items with the highest mean scores in both groups. The fasting group had a lower average score (2.88) compared to the non-fasting group (3.66). This difference was statistically significant (p=0.033). **Conclusion:** Over 53% of study patients fasted for at least 1 day during Ramadan. Interestingly, Patients who fasted had a better health-related quality of life when compared to those who did not fast. Patients with hypertension and cardiac diseases were the subjects least able to fast during Ramadan.

Introduction

Intermittent fasting during the month of Ramadan is one of the five pillars of Islam. During this time, Muslims abstain from food, drink, and oral medications from sunrise until sunset, which, in the year of this study, lasted for approximately 14 hours in Khartoum. Each year, Ramadan lasts for one lunar month. There are over 366 million patients with diabetes worldwide; 50 million of them are expected to fast in Ramadan (1, 2). The percentage of patients with diabetes fasting in Khartoum is approximately 55%. Other studies reported marked differences in the percentages of diabetic patients fasting during Ramadan. For instance, approximately 9.4% and 71.6% of type 1

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diabetes patients fasted in Morocco and Saudi Arabia, respectively (2). For type 2 diabetes, the percentage of patients with diabetes who fasted ranged from 57.8% in Turkey to 89.9% in Malaysia (2). These differences could be explained by the cultural and spiritual differences amongst the Muslim countries as well as differences in diabetes care, climate, and the country's economy. Those who are ill during this month are exempted from fasting. Uncontrolled diabetes, recent diabetic ketoacidosis, recurrent hypoglycemic episodes, and hypoglycemia unawareness are examples of conditions that result in exemptions (2). Diabetic patients' fasting increases their risk of developing acute complications such as hypoglycemia (very common), dehydration (very common), hyperglycemia (common), and ketoacidosis (uncommon) (2, 3).

Healthcare expenditure of patients with diabetes is much higher in comparison with non-diabetics. Huge sum of money is spent on diabetes-related complications. In Sudan, patients with type 2 diabetes spend an average of 175$ annually, which is approximately 9% of the average annual income of these patients. The cost of type 1 diabetes is estimated to be around 283$ per year, which is 23% of the family's annual income. The high cost of healthcare for Sudanese diabetics leads to abandoning or reducing of the insulin therapy by almost half of the patients (4).

Ideally, patients would have to visit their doctors 30-60 days prior to Ramadan to assess whether or not they are fit to fast. Yet the majority of Muslim patients with diabetes avoid visiting their doctor in fear of being instructed not to fast. Others do not perceive themselves as ill and underestimate the seriousness of their condition. The low level of awareness in Sudan, especially in the rural areas where the prevalence of the disease is 11.2% (8% in Khartoum), was observed even among patients who have experienced diabetic complications (5).

Having a chronic disease, patients with diabetes need to be assessed for treatment effectiveness and be evaluated for the effect that the disease has on their health-related quality of life (6). Previous studies showed that good glycemic control in patients with diabetes was not associated with an overall improvement in their health-related quality of life (7-12). The overall health-related quality of life in patients with diabetes can be influenced by several variables including glycemic control, economic status, comorbidities, presence of complications, and the quality of medical, psychological, and social support (13,14).

Previous studies investigating the effects of fasting during Ramadan emphasized the biochemical factors in patients with diabetes, without considering the psychosocial and financial implications. This study aimed to illuminate some of the challenges faced by diabetes patients during Ramadan based on their own experiences.

Material and methods

This is a community based cross-sectional study, which was performed in Khartoum, Sudan. For the study's primary objective, the study was designed to assess the health-related quality of life of fasting and non-fasting Muslims with diabetes during the month of Ramadan using the structured D-39 questionnaire. Secondary objectives of the study included estimating the percentage of diabetic patients who decided to fast during Ramadan using the Sudanese cohort, estimating the percentage of patients with diabetes who fasted for more than 15 days in the cohort, identifying determinants which most seriously affected patients with diabetes during the month of Ramadan, and comparing the health-related quality of life between fasting and non-fasting diabetics.

Study population

The inclusion criteria consisted of subjects 18 years of age or older with type 1 or 2 diabetes who agreed to participate in the survey. Subjects were excluded if they were younger than 18 years of age or if they did not complete the whole survey (to maintain homogeneity of the data set). Convenience sampling was used, which targeted family members of colleagues who fulfilled the study criteria. The formula $n = z^2 \cdot (p) \cdot (1-p) / c^2$ at a 95% confidence level was used to estimate the sample size.

Data collection

Data was collected via completion of a partially assisted questionnaire during August 2015 to October 2015. The data collection tool aimed to obtain demographic data and medical

history pertaining to diabetes. The health-related quality of life was assessed using a questionnaire (D-39 instrument). The D-39 questionnaire was previously used in several similar studies (But not within Ramadan frame) and was chosen for this study because it could be used to collect data from the entire diabetic population, regardless of their age, gender, and duration of the disease. A professional medical translator translated the questionnaire into Arabic. This translated version was piloted using 10 patients where a comprehension score of above 90% was achieved. Participants reported the degree to which their lives have been affected by each item, action, or event during the month of Ramadan using a scale from 1 to 7 (15). The score 1 meant the patient was not affected and score 7 meant that the patient was extremely affected. Thus, scores closer to 0 indicated a better health-related quality of life. To analyze how fasting/not fasting affects the health-related quality of life. To further investigate the overall health-related quality of life, the total score for each participant was calculated (17 being the best score and 119 being the worst). Furthermore, three categories of health-related quality of life impairment were established: mild (scores between 17 and 50), moderate (scores between 51 and 84), and severe (scores between 85 and 119).

Data analysis

The data were collected and entered into an excel spreadsheet; next they were analyzed using the SPSS software to obtain the graphs and means. SPSS was also used to perform the independent t-tests and to test for correlations. In both tests, a probability level (P-value) of < 0.05 was considered significant. To identify the effect of fasting on the health-related quality of life for diabetics, participants were divided into two groups with regards to their fasting status during this month. The means of these groups were analyzed using an independent t-test.

Results

One hundred and twelve patients with diabetes participated in this survey; 54% of them were female (n= 60) and 46% (n=52) of them were male (Table 1). The age of participants ranged from 18 to 89 years, (mean=53, SD=13.4). Duration of diabetes in

the cohort was variable; 36.7% of those who did fast (n=22) had diabetes for <5 years, while 30.8% (n= 16) of those who were unable to fast had the disease for the same period of time. 33.3% of the participants with a 5-10 year history of diabetes, were in the fasting group (n=20) vs. 7.7% (n=4) who did not fast. Thirty percent (n=18) and 61% (n=32) of the fasting group and non-fasting group had diabetes for >10 years, respectively. Therefore, a longer duration of diabetes signals that it is less likely for patients to fast during Ramadan.

Approximately 73% of patients in the fasting group were on oral hypoglycaemic agents (OHA), while 53.8% of non-fasting patients took oral agents. Approximately 46% and 17% of the non-fasting group and fasting group were on insulin +/- OHA, respectively (Figure 1). Ten percent of the fasting group dealt with the disease using lifestyle changes; none of the latter group broke their fast.

Out of the 112 study participants, 53.57 % (n= 60) were able to fast during the month of Ramadan. Thirteen percent of the fasting group fasted for less than 10 days. Only 3% of them were able to fast for 10-15 days, while 84% of the fasting group managed to fast for more than 15 days (Figure 2).

Fifty percent of study participants suffered from at least one of the following comorbidities: hypertension (HTN), cardiac disease, kidney disease, or gout, these data are shown in Figure 3. The majority of patients did not fast when they had HTN and cardiac disease (86.7%) and almost half (53.6%) of those who only had HTN did not fast (Figure 3).
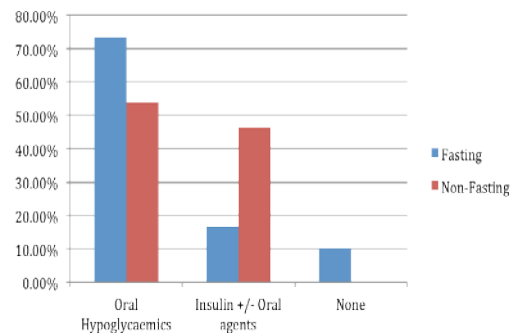

Figure 1. Percentage of fasting and non-fasting groups and their baseline type of treatment they take
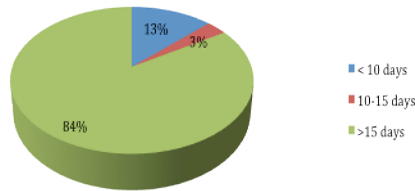
Figure 2. Percentage of days fasted out of the fasting group (Fasting group was 53.5% of the total study population).

The scores of each participant were summed for further evaluation of the degree of impairment in their health-related quality of life. A total score of 17 and 119 was the lowest and highest possible total score. The results were then arranged into three categories: mild (score between 17 and 50), moderate (score between 51 and 84), and severe (score between 85 and 119). Sixty percent of participants who were not able to fast had a total score ranging from 51 to 84 (moderate), while the majority of the participants who were able to fast (59%) had a total score ranging from 17 to 50 (mild).

Furthermore, several significant correlations (p < 0.05) in the fasting group were observed. First, younger patients were more concerned about economic issues related to the testing of their sugar levels and necessity of taking frequent rests. Older patients found it difficult breaking the fast during the fasting month. Females in this group were associated with a lower
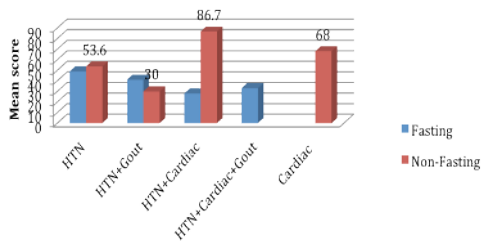
health-related quality of life due to the restrictions their diabetes places on their friends and family such as the need to eat regularly, the need to rest often, fear of hypoglycemia, fear of hyperglycemia, and diabetes in general. Embarrassment of having diabetes, insulin usage, testing their sugar levels, and having diabetes interfere with their family life were all factors associated with having recently been diagnosed with diabetes. The presence of comorbidities was associated with limited energy levels in the group. In subjects who did fast, young age and female gender were significantly associated with a higher total score (p=0.006 and 0.001, respectively) figure (4a-b).

The average score for each item in the D-39 instrument was calculated for each group (fasting and non-fasting). Furthermore, the means for each item for the above-mentioned

Figure 4-a. Mean score of Ramadan difficulties obtained from D-39 questionnaire in both fasting and non-fasting groups.

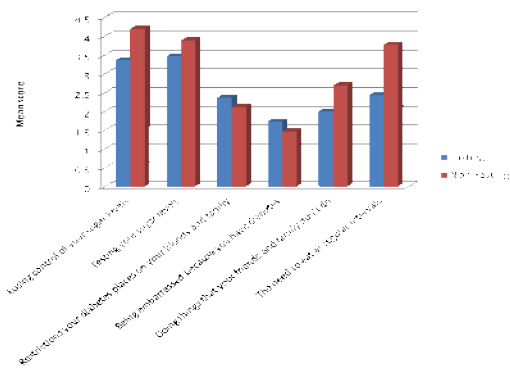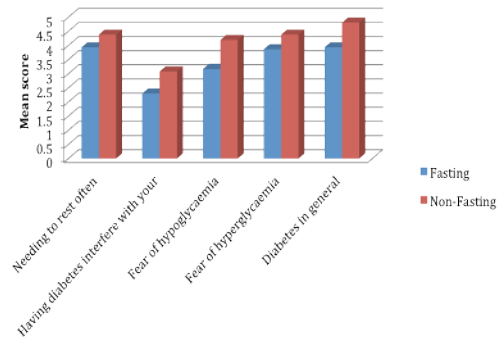**Figure 3.** Percentage and types of comorbidities associated with the fasting and non-fasting groups

Figure 4-b. Mean score of Ramadan difficulties obtained from D-39 questionnaire in both fasting and non-fasting groups.

Table1. Demographic distribution of the fasting and non-fasting groups

	Fasting		Non-fasting	
Age	N	%	N	%
<20	2	3.30%	0	0%
20-40	2	3.30%	8	15.40%
41-60	40	70.10%	30	57.70%
>60	16	23.30%	12	23.10%
Gender	N	%	N	%
Male	24	40%	28	53.80%
Female	36	60%	24	46.20%
Duration of DM	N	%	N	%
<5	22	36.70%	16	30.80%
5-10	20	33.30%	4	7.70%
>10	18	30%	32	61.50%
Treatment	N	%	N	%
Oral agents	44	73.30%	28	53.80%
Insulin +/- oral agents	10	16.70%	24	46.20%
None	6	10%	0	0%

groups were calculated. The fasting group had an average score of 2.88 (SD=0.77). The non-fasting group had a higher average score of 3.66 (SD=1.22). To test if these means were different, an independent t-test was performed (supplementary table). The independent t-test was associated with a statistically significant effect p=0.033. Thus, non-fasting subjects were associated with a statistically significant higher average score than those who did fast, which means that those patient suffer less when they fast.

Discussion

This study analyzed the HRQOL and explored the sociodemographic and disease-related variables that significantly affected the health-related quality of life (QOL) of Sudanese diabetic patients during Ramadan. Half of the participants in this study suffered from at least one comorbidity, which agrees with another study conducted in Sudan. An interesting finding in this study was that the percentage of subjects with comorbidities was higher in participants who were able to fast (56.7%) when compared to the percentage of non-fasting participants (42.8%).

The results of the present study show that the mean score of non-fasting diabetics was significantly higher than the mean score of diabetics who did fast. A higher score indicates a lower health-related quality of life. These data are consistent with a qualitative study conducted in the United Kingdom regarding fasting during Ramadan. Patel NR et.al. reported that some fasting patients felt more energetic and happier. The ability to withstand the absence of food and drink for most of the day resulted in a sense of positive mental and physical well-being. On the other hand, the inability to participate in their religious rituals with their families and community generated negative emotions. Most of the non-fasting respondents in that study felt guilty or embarrassed (16).

The presence of diabetes-related complications and the duration of diabetes were found to significantly influence health-related quality of life. Similarly, in a study conducted in the United Arab Emirates, W. Bani-Issa concluded that young age, shorter duration of diabetes, and the absence of complications were associated with a better health-related quality of life (9). In our study, we did not find any significant correlations between any of the independent variables and the overall health-related quality of life in non-fasting participants. In contrast, young age and the male gender were correlated with a worse health-related quality of life in fasting diabetics.

Moreover, W. Bani-Issa study evaluated the health-related quality of life of 200 Emirati with diabetes, who attended one of four primary health care centers in the United Arab Emirates UAE. The Arabic version of the World Health Organization health-related quality of life questionnaire (WHOQOL Brief) was used. The presence of diabetes-related complications, the duration of having diabetes, and the marital status were found to significantly influence the total HRQOL score. The presence of complications was the most influential variable influencing the HRQOL, especially the physical domain. Duration of diabetes did not influence the psychological domain. Marital status did not influence the physical and psychological domains, either (9).

Similarly, Murtada Elbagir et.al. assessed the

HRQOL in 89 insulin-treated diabetics living in Sudan. In this study, participants were between 25 and 55 years of age and had diabetes for at least 5 years. For this study, the HRQOL was assessed using a 68 item questionnaire from a medical outcome study. Only 13.5% had good metabolic control (HbA1c < 7.5%). These patients had a worse HRQOL score compared to patients with poor glycemic control. This study also found that young age, shorter duration of diabetes, and absence of complications were associated with a better HRQOL (17).

Several studies used different generic or diabetes-specific instruments or questionnaires to assess the HRQOL in patients with diabetes, including the Diabetes 39 instrument, which was used in the present study. In Sudan, 105 outpatients with type 1 diabetes mellitus, 136 with type 2 diabetes mellitus, and their healthcare providers had their health-related quality of life assessed using the WHOQOL Brief. In a study performed by Abdel W. Awadalla and his group, they concluded that type 1 diabetes patients have the lowest health-related quality of life scores, followed by type 2 diabetic. Furthermore, Abdel W. Awadalla et.al reported that having additional medical problems, a diminished sexual desire, unemployment, and being single were all factors associated with poor health-related quality of life, but illness duration was not an influencing factor here (18).

Data regarding the health-related quality of life of patients with diabetes during Ramadan fasting is still lacking. However, Salti I. et.al. suggested that fasting by patients with diabetes significantly increased their risk of developing acute complications, which hinted at a lower health-related quality of life (2). However, the health-related quality of life for patients with diabetes has been thoroughly assessed in many studies (7, 9, 18, 19).

Conclusion

This study was the first to evaluate the health-related quality of life of diabetic patients during the holy month of Ramadan. Approximately 54% of participants fasted for at least one day, and 83% of this group managed to fast for more than 15 days. The results obtained from this study showed that diabetic patients who fast during Ramadan have a better health-related quality of life when compared to non-

fasting diabetics. A longer duration of diabetes (>10 years) which was inversely proportionate with the ability of fasting, meant that the participants were less likely to fast. Those with multiple comorbidities struggled more while fasting during Ramadan. However, a larger cohort of patients should be assessed to confirm or challenge the present results. The need for psychological assessments during chronic diseases is becoming increasingly evident.

Recommendations

Health care professionals should emphasize the impact of chronic illnesses on patients. Patients with diabetes should be counselled before attempting to fast during Ramadan. Nonetheless, high risk patients should be aware of the risk of health jeopardy if they do fast.

Limitations

This study has a limited number of patients which, in order to be supported, requires future studies with larger population.

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