

British Journal of Medicine & Medical Research 5(6): 819-830, 2015, Article no.BJMMR.2015.087 ISSN: 2231-0614



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# Level of Glycemic Control and Barriers of Good Compliance among Diabetic Patients in Al-Madina, Kingdom of Saudi Arabia

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#### Authors' contributions

This work was carried out in collaboration between all authors. Author MAG designed the study, wrote the protocol, directed the work and drafted the manuscript. Author EAM collected the data, helped in designing the study and drafting of the manuscript. Author GJ managed the literature search and helped in the drafting of the manuscript. Authors AA, AAG and YA performed the data analysis, interpretation and helped in drafting of the manuscript. Author RAR collected the data and helped in data analysis. Authors RAG and AH helped in the drafting of the manuscript. All authors read and approved the final manuscript.

#### Article Information

DOI: 10.9734/BJMMR/2015/11917 <u>Editor(s):</u> (1) Anonymous (1) Ds sheriff, Faculty of Medicine, Benghazi University, Benghazi, Libya. (2) Anonymous, University of Chile, Chile. (3) Anonymous, São Paulo University, Brazil. (4) Anonymous, Aksaray University, Aksaray, Turkey. Complete Peer review History: <u>http://www.sciencedomain.org/review-history.php?iid=696&id=12&aid=6421</u>

**Original Research Article** 

Received 9<sup>th</sup> June 2014 Accepted 12<sup>th</sup> September 2014 Published 9<sup>th</sup> October 2014

## ABSTRACT

**Background:** Diabetes mellitus (DM) is an important health problem which necessitates long term follow up and control.

**Aim:** This study is designed to determine the level of glycemic control among diabetic patients in Al-Madina and to explore which type of DM shows better glycemic control. In addition, we aim to define barriers of good compliance in diabetic patients who have a HbA1c test of 7% or more.

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**Subjects and Methods:** A cross sectional analytic study was conducted and included diabetic patients participated in the campaign (Your Health is Your Life II) held in Al-Madina. Data collected by administering a questionnaire and measuring glycosylated hemoglobin (HbA1c), blood pressure, weight and height for all participants.

**Results:** Among 164 participants, only 24.4% achieved the recommended goal of HbA1c level (<7%). Higher percentage of achieving this goal is observed among type 2 diabetics (26.2%) than type 1(10.5%). Higher educational level, being on diet prescribed by a physician or a dietitian, duration of DM less than 5 years and visits of diabetic clinic within the past 3 months were associated with better HbA1c level while age above 50 and treatment with both (insulin+pills) or insulin alone were associated with lower level of control. Forgetfulness was the barrier in more than the half of patients with HbA1c of 7% or more while fear of insulin injection is the only factor which showed statistically significant difference between males and females.

**Conclusion:** High percentage of patients did not attain the recommended target of HbA1c level which is nearly comparable to results reported from many countries. This may indicate the presence of a gap between recommendations of the international guidelines and the actual practices. Regular clinic visits and higher educational level of the patients may contribute to better glycemic control.

Keywords: Diabetes mellitus; glycemic control; compliance; HbA1c; glycosylated hemoglobin.

#### ABBREVIATIONS

HbA1c: Glycosylated Hemoglobin; BMI: Body Mass Index; SAR: Saudi Riyal.

#### 1. INTRODUCTION

Diabetes mellitus is a major health problem and a common non communicable lifelong disease widely spread throughout the world. It is considered as one of the health challenges in 21st century. Nowadays, about 371 million people are diagnosed with diabetes and another 280 million at high risk of developing the disease. By 2030, it is expected to have half a billion people living with the DM [1]. According to the International Diabetes Federation, Saudi Arabia is among the countries with highest prevalence of the disease in the world, with an estimated number of 3, 414,000 patients [2]. A study, published in 2004, estimated that 23.7% of the Saudi population suffered from DM [3].

Diabetes mellitus is one of the diseases which need a lifelong treatment and tight control and adherence to advices given by doctors regarding diet and physical activity for a long time, and despite the wide spread use of self-monitoring of blood sugar, diabetic patients generally are not aware of their diabetic status [4].

Generally, hyperglycemia can cause many complications which can be divided into macrovascular (coronary artery disease, peripheral arterial disease, and stroke) and microvascular (diabetic nephropathy, neuropathy, and retinopathy). Patients with poor glycemic control are more vulnerable to microvascular diseases and tight control has an effective reduction of these complications as it has been shown in several studies [5,6].

Compliance, as defined in health care, is the extent to which a patient's attitude (taking medications, fulfillment of life style changes and keeping appointments with doctors) concurs with the health care providers for health and medical advice [7].

Glycemic control and patient compliance in diabetes has been a matter of concern of health professionals and clinical researchers in the past two decades. For this reason, many studies have explored some associated determining factors which can be sociodemographic elements such as (age, gender, educational level, and marital status) and others like patients' beliefs and motivation towards the therapy, negative attitude, patient-prescriber relationship, awareness of health issues, and patient's knowledge [8].

As far as we know, there is little information about glycemic control and these factors and no information about the compliance of diabetics in Al-Madina city in Saudi Arabia. For this reason, we find this study paper represents a chance to supply the health authorities of Al-Madina with information about this issue and also to complete our efforts in the campaign to increase the awareness of the relevance of tight glycemic control among the general population. Therefore, this research study was conducted to evaluate the prevalence of poor control and compliance of diabetic patients in Al-Madina and to identify the factors associated with better compliance. In addition, We included both patients with type 1 and 2 diabetes while most reports included only the latter.

# 2. OBJECTIVES

- 1. To determine the level of glycemic control among diabetic patients of both types 1 and 2 that participated in the campaign (Your Health is Your Life II) and to explore which type of DM showed better glycemic control.
- To study the association between sociodemographic factors, life style and associated medical conditions and level of glycemic control in those diabetic patients.
- 3. To define barriers for good compliance in diabetic patients who had a HbA1c test of 7% or more.

## 3. METHODOLOGY

## 3.1 Type of the Study

Observational cross sectional analytic study.

## 3.2 Study Population

The study included Diabetic patients who participated in the campaign (Your Health is Your Life II) which was held in Al-Madina in the period from Tuesday 9/4/2013 to Thursday 18/4/2013 based on the following inclusion and exclusion criteria.

#### 3.2.1 Inclusion criterion

- 1. Type 1 and 2 diabetic patients based on the clinical history of the disease who diagnosed in health clinic at least six months ago, and they are on antidiabetic medication prescribed by the physician for at least 3 months.
- 2. Age of 18 or more.
- 3. Accept voluntarily to participate in the study.

#### **3.2.2 Exclusion criterion**

- 1. Female participants with gestational diabetes mellitus
- 2. Diabetic participants below the age of 18 because patients under this age have additional factors related to their adherence to diabetic treatment which may affect the study results such as their dependence on their family members.
- 3. Other conditions that could limit the knowledge of their condition or treatment such as advanced aged, cognitive dysfunction, etc.

## 3.3 Data Collection

The data was collected during the events of the campaign (Your Health is Your Life II) which was organized by Taibah Medical Club (TMC) and lasted for 11 days. We conducted this study by introducing a self administered questionnaire prepared on Google documents software by using mini-Ipad devices. Members of TMC collected the data and measured glycosylated hemoglobin (HbA1c) by using kits of A1CNow from Bayer, blood pressure, height and weight for all participants. This was conducted mostly at AI-Rashid Mall and through scheduled visits to some governmental organizations, high schools and diabetic center in AI-Madina.

## 3.4 Data Analysis

After transferring the data from Google documents software to excel where it was coded and cleaned, data was transferred to software package used for statistical analysis (SPSS) version 21. On SPSS program, descriptive analysis was done to determine the level of glycemic control among participating patients and then followed by inferential statistics using the appropriate test of significance for qualitative and quantitative data. Chi square test was used in this study and P value of 0.05 was considered as a cut of point for the level of significance. Participating diabetic patients were divided into two groups: patients with HbA1c of 7% or more and those with less than 7%. This classification based on the American was Diabetes Association (ADA) guidelines which consider the reasonable HbA1c goal for diabetic patients to be less than 7% as lowering the HbA1c to this level has been associated with a decrease in the microvascular complications of DM as well as long term reduction in macrovascular disease if implanted soon after the diagnosis.

#### 3.5 Ethical Consideration

Verbal consent was obtained from the participants in this study after explaining that their personal information will be confidential and for the purpose of scientific research only.

Participants who showed high HbA1c level were given advice by the doctors present at the campaign about the importance of diet and physical activity for the diabetic patients. In addition, their HbA1c measurements were written down for them and advised to meet their doctors at the diabetic centre.

#### 4. RESULTS

A total number of 164 diabetic patients divided as 101 (61.6 %) males and 63 (38.4%) females participated in the study, with 19 (11.6%) had type 1 DM while 145 (88.4%) had type 2.The mean HbA1c levels of participants was 8.4% (SD  $\pm$ 1.9).

Fig. 1 displays that only 40 participants (24.4%) have HbA1c level less than 7% while 124 (75.6%) of them have HbA1c of 7% or more.

Fig. 2 displays that recommended levels of HbA1C achieved more in patients with type 2 (26.2%) comparing to just (10.5%) in type 1.



#### Fig. 1. Overall percentage of glycemic control of diabetic patients based on HbA1c test

Table 1 shows that there are statistically significant differences between participants with HbA1c level below 7% and those with 7% and more regarding age and educational level. Patients above 50 years old have lower percentage (17%)in achieving the recommended levels of HbA1C followed by those below 30 years old (20%) and lastly participants between 30 and 50 (37.5%). In addition, patients with higher education showed better results (36.4%) in achieving the recommended goals in comparing to illiterates (22.2%) and those with only high school (8.1%). Other sociodemographic factors discussed in this study showed no statistically significant differences.



Fig. 2. The glycemic control among participating patients with type 1 and type 2 DM based on HbA1c test

Variables	Less than 7 %		7 % or mo	ore	P value
	Ν	%	Ν	%	
Age					
< 30	4	20	16	80	
30– 50	21	37.5	35	62.5	.018*
>50	15	17	73	83	
Nationality					
Saudi	30	22.2	105	77.8	.163
Non Saudi	10	34.5	19	65.5	
Gender					
Male	26	25.7	75	74.3	.61
Female	14	22.2	49	77.8	
Marital Status					
Single	3	18.8	13	81.2	
Married	35	25	105	75	.956
Divorced	1	25	3	75	
Widow/ed	1	25	3	75	
Educational level					
Illiterate	8	22.2	28	77.8	
Primary/intermediate	9	25	27	75	.021*
school					
High school	3	8.1	34	91.9	
Higher education	20	36.4	35	63.6	
Occupation					
Employed	25	25.3	74	74.7	
Non emp loyed	13	24.1	41	75.9	.873
Student	2	18.2	9	81.8	
Residence					
Urban	38	24.5	117	75.5	.876
Rural	2	22.2	7	77.8	
Family income					
<3000 SAR **	6	25	18	75	
3000 – 9000 SAR	16	23.2	53	76.8	.954
>9000 SAR	18	25.4	53	74.6	

Table 1. Association between Socio-demographic factors and the level of glycemic control based on HbA1c test

There is statistically significant difference, \*\* Saudi Riyal

Table 2 shows that there is statistically significant difference between participants with HbA1c level below 7% and those with 7% and more regarding being on diet. Participants who followed a diet prescribed by a dietitian or physician had better results (42.9%) in achieving the recommended goals of HbA1c when compared to others who are not on diet prescribed by them (29%) or not on diet at all (18.1%). Other factors discussed in this study showed no statistically significant differences.

Table 3 shows that there are statistically significant differences between participants with HbA1c level below 7% and those with 7% and more regarding duration of DM, type of treatment and timing of the last clinic visit. Participants who have been diagnosed before 5 years and

patients who had previous visit to the diabetic clinic within the past 3 months had better percentages in achieving the recommended goals of HbA1c which are (43.5%), (30%) respectively. In addition, participants on both (insulin and pills) or those with only insulin treatment have lower results (5%), (10.3%) respectively in achieving the recommended goals when compared to those on only pills (33.3%). Other factors discussed in this study showed no statistically significant differences.

Fig. 3 demonstrates that forgetfulness was the barrier of good compliance in more than half of patients who showed HbA1c of 7% or more. Patients also reported other factors such as timing of taking treatment (27%), lack of reminding (20.2%), difficulties in dealing with

insulin injections (18%) and side effects of treatment (16.9%) while high costs of the drugs was on the bottom of the list with only 3.4% of participants.

Based on Table 4, only (fear of insulin injection) showed statistically significant difference between males and females. Five females (83.3%) reported this cause in comparing to only one male (16.7%). The remaining factors were higher in males than females.

#### 4. DISCUSSION

Diabetes mellitus (DM) is considered as a major public concern throughout the world especially in

Saudi Arabia. It is one of the diseases that need a long term follow up and control to avoid its devastating complications such as diabetic nephropathy, retinopathy, cardiovascular disease [9] and premature death [10].

Our results showed that 75.6% of diabetic participants in the study which included both types (1 and 2) have a HbA1c level of 7% or more which is beyond the targeted level determined by the ADA. Although this percentage is huge and alarming, it is not different from other results obtained in other studies. A study conducted in Al-Hasa region showed that 67.9% of the participants had

 
 Table 2. Association between the level of glycemic control in study subjects and variables of life style and associated medical conditions

Variables	Less tha	n 7 %	7 % or m	ore	P value		
	Ν	%	Ν	%			
Family history of DM in 1 <sup>st</sup>	<sup>t</sup> degree rela	atives					
Yes	27	24.8	82	75.2			
No	13	23.6	42	76.4	.873		
On diet							
No	19	18.1	86	81.9			
Yes, by physician or	12	42.9	16	57.1			
dietitian					.02*		
Yes, not by physician or	9	29	22	71			
dietitian							
Eating fast food							
None	13	16.5	66	83.5			
Once or twice a week	23	33.8	45	66.2	.05		
3 or more a week	4	23.5	13	76.5			
Exercise							
None	18	23.7	58	76.3			
Once or twice a week	15	34.9	28	65.1	.106		
3 or more a week	7	15.6	38	84.4			
Smoking							
Non smoker	34	23.9	108	76.1			
Smoker	3	17.6	14	82.4	.144		
Ex-smoker	3	60	2	40			
Hypertension							
hypertensive	19	26	54	74	.662		
Non hypertensive	21	23.1	70	76.9			
Dyslipidemia							
Yes	16	22.9	54	77.1	.693		
No	. 24	25.5	70	74.5			
Medications for dyslipidemia							
Yes	13	21.7	4/	/8.3	= 0 /		
No	3	30	/	70	.561		
BMI^^		107	-				
Underweight	1	16.7	5	83.3	a 1 <b>-</b>		
Normal weight	/	17.5	33	82.5	.617		
Overweight	15	26.8	41	/3.2			
Obese	1/	27.9	44	/2.1			

\* There is statistically significant difference, \*\*Body Mass Index

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Fig. 3. % of barriers of good compliance in diabetic patients who had HbA1c test of 7% or more

Variables	Less than 7 %		7	% or more	D value
Valiables	N	%	<u> </u>	% %	
Duration of diagnosis for DM	••		••		
Less than 5 years	20	43.5	26	56.5	
5-10 years	11	21.6	40	78.4	<.001*
More than 10 years	4	7	53	93	
Type of treatment for DM	-	-			
Pills	35	33.3	70	66.7	
insulin	4	10.3	35	89.7	.002*
Both (insulin+ pills)	1	5	19	95	
Complications of DM	-	-			
Yes	18	18.8	78	81.2	.18
No	16	28.1	41	71.9	
Hospitalization duo to DM					
Yes	5	12.5	35	87.5	
No	34	27.6	89	72.4	.051
Last clinic visit	•				
Before 3 months	30	30	70	70	.037*
3 months or more	10	15.6	54	84.4	
Owning a glucometer at home	-		-	-	
Yes	23	21.3	85	78.7	
No	15	28.3	38	71.7	.325
Health education about DM					
Yes	29	25.4	85	74.6	
No	10	20.8	38	79.2	.531

Table 3.	Association between some fa	actors related to DM and the level of glycemic control i	in
	study sub	bjects based on HbA1c test	

There is statistically significant difference

Variables	Male			Female	P value
	Ν	%	Ν	%	
Forgetfulness	26	56.5	20	43.5	.547
Presence of more than one	7	70	3	30	.475
treatment for DM					
Side effects	11	73.3	4	26.7	.233
High cost	2	66.7	1	33.3	.798
Presence of treatment for	8	66.7	4	33.3	.589
diseases other than DM					
Timing of taking treatment	14	58.3	10	41.7	.887
Lack of reminding	10	55.6	8	44.4	.699
Difficulties in dealing with insulin	10	62.5	6	37.5	.791
Fear of insulin injection	1	16.7	5	83.3	.027*

 Table 4. Association between gender and barriers of good compliance in diabetic patients who had HbA1c test of 7% or more

\*There is statistically significant difference

HbA1c of 7% or more [11]. Another one held in India was much similar to our results with 75% of participants exceeded the targeted level [12]. However, we had higher percentage of poor glycemic control compared to some countries like Hong Kong [13] and Mexico [14] that have percentages of 59.61% and 65% respectively.

In addition, the results showed better glycemic control among type 2 diabetic patients with 26.2% of them achieved the targeted HbA1c level in comparing to only 10.5% among those with type 1.Some studies have similar results regarding glycemic control among type 2 diabetic patients such as a study included 28 health centers distributed throughout the kingdom of Saudi Arabia [15] and showed that 27% of the participants reached the target HbA1c of < 7%. In contrast, information about type 1 remains very few. However, a study published in 2013 demonstrated that only 9.5% of type 1 diabetics have HbA1c lower than 7% [16]. This low level of glycemic control obtained in type 1 DM can be explained by some results in our study such as longer duration of DM and treatment with insulin. Among type 1 diabetics, 63.1% have duration of the disease more than 5 years and only 10.3% of patients treated with insulin achieved the targeted HbA1c level in comparing to 33.3% among those on pills. Some studies found that patients on insulin are the least satisfied with their treatment which could be related to the fact that taking a pill is more comfortable than injecting insulin [17,18].

Regarding socio-demographic factors discussed in our study, age of the patients and their educational levels showed statistically significant differences between the two groups, participants of HbA1c below 7% and those with 7% or more. 83% of participants with old age (> 50 years old) have a HbA1c level of 7% or more, which is consistent with a result of a study published recently in India [19]. In addition, the younger age (< 30 years old) showed a nearly comparable percentage (80%) to the old age group which is supported by a study published in 2003 [20]. Based on our results, this could be explained by that the majority of this age group has type 1 DM (80% of them) which showed poor glycemic control comparing to type 2. Besides, patients with higher education are found to be significantly associated with achieving the targeted goal of HbA1c (36.4% of them) in comparing to illiterates and those with high school education (22.2%, 8.1%) respectively. Many studies stated that patients with high educational levels significantly showed higher compliance rates [11,21]. Other sociodemographic factors showed no statistically significant differences. Similar results are found in other studies regarding gender [22] and marital status [11,19].

Concerning life style factors, being on diet is the only factor that showed a significant difference between diabetic patients with HbA1c (Less than 7 %) and those with HbA1c (7 % or more). In our study, 81.9% of diabetic patients with HbA1c of 7% or more were not on diet as they didn't follow the diet instructions which were recommended by their dietitians. On the other hand, 42% of diabetic patients who are following the dietitian's eating plan got better results and this is proved by a study published in 2012 which states that satisfied patients have better adherence to dietary habits recommendations [23].

A Study published in 2010 confirms our result regarding being on diet as it states that 65.1% of the study population who had HbA1c  $\geq 7\%$  are not following eating plan as recommended by dietitians [24].

We didn't find statistical significant differences regarding family history of DM in 1st degree relatives, eating fast food, exercise, smoking, hypertension, dyslipidemia, medications for dyslipidemia and BMI. However, a study published in 2012 states that non adherence to instructions on exercise is associated significantly with poor compliance [11]. We could explain our results regarding physical activity and eating fast food by the nature of elderly people in our society. We found that the highest percentage of diabetic patients who have HbA1c level of 7% or more was in the age group above 50 years (83% of them) and in our society people of this age group tend to do less physical activity and exercise and they also don't prefer to eat fast food.

Regarding hypertension and dyslipidemia, there were no significant differences between diabetic patients of HbA1c 7% or more and those of level less than 7%. This result is more or less similar to the study conducted in Al-Hasa, Saudi Arabia as it states that associated chronic diseases are not significantly associated with non-compliance [11].

Concerning factors related to DM, we found highly statistically significant difference between the two discussed groups in our study regarding duration of diagnosis of the disease. Only 7% of people who are diagnosed more than 10 years ago and 21.6% of those with duration between 5 to 10 years have reached the targeted level of HbA1c. A recent study published in 2013 found a significantly higher risk of the non-compliance among those who had diabetes for five years or more [19]. Similar observation is also noted in other studies [24, 25]. There was also significant difference regarding the type of treatment. Only Small percentage of participants on both (insulin and pills (5%)) and patients on insulin alone (10.3%) have attained the recommended goals of HbA1c. Same results are obtained in other studies [11,19]. This can be explained by preferring of patients to have a single drug regimen instead of multiple ones [26]. In addition, it could be duo to a wrong technique of injecting insulin or unavailability of someone at home who can help in administering the injection [27].

Another acceptable explanation is that patients on insulin treatment usually tend to have longer duration of the disease with more complications.

We also found a statistical significant difference between the two groups regarding last clinic visit and follow-up as patients who had a visit to the diabetic clinic within the last 3 months showed higher percentage of attaining the recommended HbA1c levels than others. This may be supported and explained by an interesting study which stated that significant improvement in glycemic control was obviously associated with immediate feedback of the results of HbA1c at the time of patient encounters [28].

In our study, forgetfulness was the most common barrier of good compliance in more than half of participants with HbA1c level of 7% or more. Many other studies reported the same result [19], [29]. On the other hand, high costs of treatment were on the bottom of the list because Saudi people who constitute the majority of study population are supplied with treatment freely in the primary health care units.

Many barriers lie behind the poor compliance in diabetic patients who had HbA1c test of 7% or more. Among these factors, fear of insulin injections was the only barrier of statistically significant difference between males and females and it was more associated with females (83.3%). Study published in 2009 was more or less similar to our result. It states that 22% were in 'fear of needle' group and of these, 71.8% were females [30].

We didn't find significant differences between males and females regarding other factors discussed in the study but in general speaking all of these factors were higher in males than females.

Regarding points of strength in our study, all the questionnaires were collected by the researchers themselves and some of TMC members under the supervision of one of the research staff members. The parts of the questionnaire were explained to the diabetic patients. In Addition, The Campaign was held in Al-Rashid Mall where diabetic patients of different age groups were there and participated in the study. Besides that, we collected many cases from high schools and the diabetic centre in Al-Madina. The study didn't focus on DM type 2 only, as many similar studies did, so type 1 was included in the study to make comparison between the two types.

Concerning limitations of the study, the study population is relatively small although over 900 persons including diabetics participated in the campaign. This is because this study is of cross sectional type targeting only diabetics and some participants (n=22) are excluded for not matching the inclusion criteria. In addition, the sample of type 1 is small. It represents only 11.6% of the whole study subjects but the study is of cross sectional type and we didn't like to ignore this percentage. In addition, this percentage of type 1 reflects the normal percent of this type in the society in comparing to type 2.

#### 5. CONCLUSION AND RECOMMENDATIONS

High percentage of patients did not reach the recommended target of HbA1c level which is nearly similar to results reported from many countries. This may indicate the presence of a gap between the actual practices in health care facilities and the recommendations of the international guidelines. Regular clinic visits and higher educational level of the patients may contribute to better glycemic control.

More efforts should be provided through intersector cooperation between ministries of health, education and information and culture to increase the awareness regarding this problem. In addition, health care professionals are urged to do more research studies to identify causes of poor glycemic control and to find best ways to act with this issue especially in type 1 diabetic patients.

## ETHICAL APPROVAL

The study has an approval from research and human ethics committee in Taibah University.

## ACKNOWLEDGEMENT

We would like to express our gratitude and appreciation to all those who gave us the possibility to complete this study. We are very grateful to Taibah Medical Club for arrangement of this campaign and providing us with the kits of HbA1c. We also would like to acknowledge with much appreciation all TMC members for their crucial role in helping us in the collection of data. In addition, we are very grateful to the supervisor of the research committee of our campaign Dr. Tamer Hifnawy (Associate Professor of Public Health, College of Dentistry, Taibah University) for his great efforts and encouragement.

Special thanks also go to Diabetic Center in Al-Madina and the participants in this study for their cooperation with us during the collection of samples.

#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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