

Compliance of Diabetic patients

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Abstract:

Background: Diabetes is likely to be the fifth leading cause of death. Global excess mortality attributable to diabetes is estimated at 2.9 million deaths which is equivalent to 5.2% of world all-cause mortality. Compliance with medical advice is essential for controlling the disease; it is affected by many factors related to the patient, the disease, the physician and the family.

Objective: To assess the level of diabetic patients' compliance with diet, drugs and visits, and to assess its effect on the disease control through certain indicators.

Methods: A total of 300 diabetic patients from different age categories, both males and females, were included in this study. The patients are usually either self-referral or referred from other hospitals, primary health care centers, governmental general practice clinics or private clinics. A questionnaire form was constructed to collect data about the demographic characteristics of the patients, about diet and medications. Files of the patients were reviewed to have an idea about their compliance.

Results: Compliance with diet was medium in half of the patients, while with drugs; it was good in 60.3%, and 38.7% had good compliance to visits. The best compliance with diet (38.2%) was seen in the age group 40-49 year while the least (19.2%) was in the age group (30-39) [$\chi^2=2.65$, $P>0.05$], 37.4% of the patients who are using oral hypoglycaemic agents, and 36.7% of those using insulin had good compliance with diet ($\chi^2=7.10$, $P<0.05$).

Conclusion: We can conclude from this study that the diabetic patients (represented by the study sample) have poor compliance with diet and visits, the duration of the disease was the most common variable found to predict compliance.

Key words: Diabetic, compliance, Iraq

Introduction:

An estimated 30 million people world-wide had diabetes in 1985¹, by 1995, this number had shot up to 135 million², in 2006, according to the World Health Organization, at least 171 million people worldwide suffer from diabetes^[3]. The

number is expected to rise from the current estimate to 220 million in 2010 and 300 in 2025. This rise is predicted to be in virtually every country throughout the world with greatest expected increases in the developing countries, particularly Asia².

Diabetes is likely to be the fifth leading cause of death. Global excess mortality attributable to diabetes is estimated at 2.9 million deaths which is equivalent to 5.2% of world all-cause mortality in the year 2000: 1 million deaths in the developed countries and 1.9 million deaths in the developing countries⁴. Data from countries of Eastern Mediterranean Region (EMR) illustrated that the diabetes prevalence rate for adults is 7.7%. However, this figure rises to between 12% and

20% for older age groups in urban communities and in Gulf area. A report done by King et al tells that the estimated prevalence of diabetes in Iraq is 6.0%².

Compliance of diabetic patients with medical advice is essential for controlling the disease; it is affected by many factors related to the patient, the disease, the physician and the family⁴.

The aim of this study is to assess the level of diabetic patients' compliance with diet, drugs and visits, and to measure the effect of this compliance on the disease control through certain indicators.

Patients and Methods:

Study design: This is a cross-sectional study, with an analytic element.

Study setting: The study was conducted during the period from January through July 2006 in the National Diabetes Center/ Al- Mustansiriya University/ Baghdad.

The National Diabetes Center is one of the main centers for diabetes in Iraq, located in Al –Karkh district/Baghdad City near Al-Yarmouk teaching hospital, and was established in 1993. It provides medical services to 70-100 patients per day. It is a research center manned by number of specialist (physicians, dietitians, ophthalmologists, pediatricians, obstetricians, sonarist, neurologist and endocrinologist). It includes a complete out-patient clinic, pharmacy, advanced laboratory, library and Internet.

The patients are usually either self-referral or referred from other hospitals, primary health care centers, governmental general practice clinics or private clinics.

A questionnaire (data collection) form was constructed to collect information about the patients. It includes the following:

- Personal and demographic data including name, age, gender, address, education marital status, and employment.
- Disease characteristics: type, duration, complications and family history.
- Drugs: type of medication, doses and time of administration.
- Investigations:: fasting blood glucose (below 140 mg/dl is good control, above 140 mg/dl is bad control), HBA1c (below 7 % is good, 7-8 % accepted and above 8% is bad) according to ADA⁵.
- Compliance with diet regimen was graded as: good, medium, and poor depending on the reported adherence to the prescribed dietary regimen by the diabetic patient, which was further evaluated by metabolic control. Good compliance is recorded when the patient strictly follows the prescribed dietary regimen, medium when follows the regimen sometimes, and poor when he does not follow at all.
- Compliance with anti-diabetic drugs was assessed by the extent of adherence of the patients to the prescribed doses of medications. Good compliance was recorded when the patient takes all his/her medications in accordance with the prescription, medium if misses 1-3 doses per month and poor when misses more than 3 doses per month.
- Compliance by diabetic patients attendance to the clinic was judged in accordance with the guidelines put by the National Quality Assurance Protocol, Ministry of Health, and Saudi Arabia³ based on the number of visits by the diabetic patient during a 6 month period. Good compliance was recorded when the patient attends the clinic more than two times, medium when attends twice, and poor compliance when the patient makes only one visit during 6 months. In assessing the degree of compliance with the visits, the investigator used to look at the dates of the patients' previous visits then follow them up.

Sample and sampling technique: A total of 300 diabetic patients from different age categories, both males and females, were included in this study.

A convenient non random sampling technique was used by pooling all the diabetic patients attending the center (during defined days) throughout the period of the study.

Inclusion criteria:

- 1- Patient with type 1 or type 2 diabetes mellitus.
- 2- Age above 18 year and below 75 years (as children are family-dependant, besides, they have their own pediatric diabetic clinic).

Exclusion criteria:

- 1- Gestational diabetes.
- 2- New registrations (after starting the data collection).
- 3- Severe medical illness including physical or mental handicaps.

The researcher used to start the interview by telling the patients the aim of the study, giving them the choice to participate, and taking their verbal consent. After taking the information and filling the form, the researcher used to look over the patients' files to see the date of their previous visit and observes whether he/she had committed to the date of the next visit.

The data was collected by making three full day visits to the centre per week, collecting about 6-7 patients per day through a direct interview which usually takes 30-45 minutes to be accomplished. The files were reviewed to examine the relationship of compliance to diet, drugs and visits to some variables related to the patients and disease characteristics, and to some biochemical investigations to confirm diabetes control (fasting blood glucose, HBA1c). The patients were followed up for 2-3 months to confirm their compliance to visits.

A Pilot project was implemented on a sample that includes ten patients, to estimate the time needed for the interview and the difficulties in the questions. Accordingly; modifications were done to make the questions shorter, clearer and easier to understand. This sample was excluded from the study sample.

Statistical analysis was done using SPSS version 12. Chi-square test was used. Differences between observations were considered significant at P value <0.05.

Results:

The sample composed of 300 adult diabetic patients; 159 (53%) females and 141 (47%) males. The age ranged from 18 to 75 years, with a (mean \pm SD) of (49.5 \pm 14) years. The highest number (28.7%) was seen in the age group 50-59, (**Table 1**).

Table (2) shows the compliance pattern of diabetic patients with diet, drugs and visits; compliance with diet was medium in half the patients, while with drugs; it was good in 60.3%, while only 38.7% had good compliance for visits.

Compliance with diet: Females and males had relatively similar levels of compliance with diet (37.7%) and (34.0%) respectively ($\chi^2=2.75$, $P>0.05$). Regarding the age; the best compliance with diet (38.2%) was seen in the age group (40-49 year) while the least (19.2%) was in the age group (30-39) ($\chi^2=2.65$, $P>0.05$). No significant statistical association was found with sex and age. Primary school graduates showed poor compliance with diet (22.6%) while university (and higher) graduates showed the highest degree of compliance with diet (40.7%), ($\chi^2=9.5$, $p>0.05$). The association was statistically not significant. Regarding the type of DM, patients with type 1 were relatively more strict with diet (39.4%) than those with type 2 DM (34.5%) ($\chi^2=5.00$, $P>0.05$).

Only (19.5%) of patients with history of more than 10 years showed poor compliance with diet, while 43.4% had good compliance ($\chi^2=17.1$, $P<0.05$). In respect to the medication; 37.4% of patients using OHA and 36.7% of those using insulin had good compliance (**$\chi^2=7.10$, $P>0.05$**). Chi-square was significant only for duration of diabetes.

Regarding the effect of compliance on FBG and HBA1C; 36.1% of those with good diet compliance had FBG equal to or less than 140 mg/dl, while 78.6% of those with poor diet compliance had FBG more than 140mg/dl. ($\chi^2=9.002$, $P<0.05$). A significant statistical association was found between FBG and diet compliance, 38% of patients with good diet compliance had HBA1c less than 7%. ($\chi^2=5.62$, $P>0.05$). **Table (3)**

Compliance with drugs: Table (4) shows that 29.8% of those with good drug compliance had FBG level equal to or less than 140 mg\dl, while 72.3% of those with poor drug compliance had FBG more than 140 mg\dl. ($\chi^2=5.7$, $P>0.05$). There was no significant association between FBG and compliance with drug. Twenty-seven percent of patients with good drug compliance had HBA1c less than 7 %.($\chi^2=5.2$, $P>0.05$).

Compliance with visits: Table (5) shows that 26.7% of those with good visits compliance had FBG less than 140 mg/dl, while 73.3% of them had FBG more than 140 mg/dl. ($\chi^2 =3.1$, $P>0.05$). There was no significant association between FBG and compliance with drug. Forty-eight percent of patients with poor visits compliance had HBA1c more than 8% ($\chi^2=5.2$, $P>0.05$).

Table 1- Age and sex distribution of the sample

		No.	%
Gender	<i>Male</i>	141	47.0
	<i>Female</i>	159	53.0
Age (Year-old)	< 30	40	13.3
	30– 39	26	8.7
	40 – 49	63	21
	50 – 59	86	28.7
	≥ 60	85	28.3
Total		300	100.0

Table 2- Compliance with diet, drugs and visits.

	Good¹		Medium²		Poor³		Total
	No.	%	No.	%	No.	%	
Compliance with diet*	108	36.0	150	50.0	42	14.0	300
Compliance with drugs**	181	60.3	72	24.0	47	15.7	300
Compliance with visits***	110	36.7	74	24.7	116	38.7	300

*Assessment of compliance with diet depends on the reported adherence to the prescribed dietary regimen by the diabetic patient:

Good¹: when the patient strictly followed the prescribed dietary regimen, medium²: sometimes did not follow the regimen, poor³: when he/she did not follow the regimen at all.

**Compliance with drugs was assessed by the extent of adherence of the diabetic patients to the prescribed doses of medications:

Good¹: when the diabetic patient took all his/her medications in accordance with the prescription, medium²: when he/she missed 1-3 doses per month, poor³: when he/she missed more than 3 doses per month.

***Compliance with visits is based on the number of visits by the diabetic patient during a 6month period:

Good¹: Good compliance was recorded when the diabetic patient attends the center on more than two occasions, medium²: when the patient attends on two occasions, poor³: when the patient attends the center only once during 6 months.

Table 3- The effect of compliance with diet on FBG and HBA1c

		Compliance with Diet						P value
		Good		Medium		Poor		
		No.	%	No.	%	No.	%	
FBS mg/dl	≤ 140	39	36.1	30	20	9	21.4	$\chi^2=9.002$ $P<0.05$
	>140	69	63.9	120	80	33	78.6	
HbA_{1c} (%)	<7	31	38.7	34	22.7	10	23.8	$\chi^2=5.62$ $P>0.05$
	7-8	41	38.0	45	30.0	13	31.0	
	>8	36	33.3	71	47.3	19	45.2	

Table 4- The effect of compliance with drugs on FBG and HBA1c

		Compliance with Drugs						P value
		Good		Medium		Poor		
		No.	%	No.	%	No.	%	
FBS mg/dl	≤ 140	54	29.8	11	15.3	13	27.7	$\chi^2=5.7$ $p>0.05$
	>140	127	70.2	61	84.7	34	72.3	
HbA_{1c} (%)	<7	49	27.1	14	19.4	12	25.5	$\chi^2=5.92$ $P>0.05$
	7-8	65	35.9	21	29.2	13	27.7	
	>8	67	37.0	37	51.4	22	46.8	

Table 5- The effect of compliance with visits on FBG and HBA1c

		Compliance with Visits						P value
		Good		Medium		Poor		
		No.	%	No.	%	No.	%	
FBS (mg/dl)	≤ 140	31	26.7	24	32.4	23	20.9	$\chi^2=3.10$ $P>0.05$
	>140	85	73.3	50	67.6	87	79.1	
HbA_{1c} (%)	<7	31	26.7	16	21.6	28	25.5	$\chi^2=4.62$ $P>0.05$
	7-8	41	35.3	29	39.2	29	26.4	
	>8	44	37.9	29	39.2	53	48.2	

Table-6- Relation between duration / medication and compliance

		<i>Compliance with visits</i>						<i>Total</i>	<i>P Value</i>
		<i>Poor</i>		<i>Medium</i>		<i>Good</i>			
		<i>No.</i>	<i>%</i>	<i>No.</i>	<i>%</i>	<i>No.</i>	<i>%</i>		
<i>Duration</i>	<i><5years</i>	40	35.7 %	22	19.6 %	50	44.6 %	112	$\chi^2=3.7$ $P>0.05$
	<i>5-10years</i>	29	38.7 %	21	28.0 %	25	33.3 %	75	
	<i>>10years</i>	41	36.3 %	31	27.4 %	41	36.3 %	113	
<i>Medication</i>	<i>Oral hypoglycemic</i>	62	35.6 %	41	23.6 %	71	40.8 %	174	$\chi^2=1.17$ $P>0.05$
	<i>Insulin</i>	41	37.6 %	28	25.7 %	40	36.7 %	109	
	<i>Both</i>	7	41.2 %	5	29.4 %	5	29.4 %	17	

Discussion:

Measuring the compliance of diabetic patients is a complex issue because it includes several important aspects of diabetic self-care activities such as the extent of adherence to dietary regimen, drugs, and visits. Cost and feasibility of the different means of assessing compliance are also important when deciding whether to use self-reported, observational, or biochemical methods ⁴.

The present study showed that the highest percentage of diabetes was seen in the age group (50-59 year) with a mean age of (49.50± 14). In a study in Saudi Arabia a higher mean age (54.2±12.8) was found [4]. In developing countries, the majority of people with diabetes are in the age group (45- 64 years) ⁶.

The current study showed that the study sample had a relatively high mean **FBG** level at (183.4 ± 73.9) mg/dl. Similar findings were reported in Al Manhal primary health care center in Saudi Arabia ³, they found that the mean FBG is (189 ± 63.6). In this study the mean **HBA1c** was (8.1 ± 1.7), Derr et al in their study in Maryland cited that the mean HBA1c is (7.66 ± 1.11%) ⁷.

Because of the lack of standard methods for assessing various aspects of compliance and the problem of comparing such methods and measurements, diabetic research investigators have had difficulties in making conclusive statements about compliance with various diabetic regimens ⁸. In our study, compliance with drugs was much better than compliance with diet and visits, this goes with other studies which observed that compliance is better with medical aspect of a regimen (medication) than with life style aspect of diabetic regimen, such as diet and exercise. ^{9,10}

Thirty-six percent of the studied sample had good compliance with diet; this poor adherence to dietary regimen could be attributed to the lack in dietary knowledge that required informative educational programs. Compliance with dietary advice could be improved by spending more time and efforts on dietary education and by providing appropriate educational materials ¹¹. The study of Saudi Arabia found that 40% of their sample has good compliance with diet ³, while another study reported that 59.7% of the patients were assessed as having good behavior with regard to dietary compliance ¹².

The study showed that females and males have relatively similar levels of compliance with diet, while Khattab et al reported in their study that males have better compliance than females, they also found that none of the socio-demographic characteristics has a significant relationship to compliance with diet except for sex ³.

Thirty-eight percent of the patients in the age group (40-49 year) had good compliance with diet. Similarly, Johnson et al in their study in South Central Los Angeles found that younger patients are less likely to follow the recommended dietary regimen¹³.

Patients with high education showed relatively good compliance with diet (40.7%); this gives the impression that educated people tend to learn more about their disease, while patients with low literacy have poorer knowledge and worse clinical outcome. Similar findings were reported by Johnson et al¹³ who found that patients with lower education are more likely to consume fat and sweet.

The current study showed that both oral hypoglycemic agents and insulin had no significant association with diet compliance. The same result was seen in the Saudi Arabia study where neither the number of drugs nor the type were found to have any significant relationship with the degree of compliance to diet³.

Unexpectedly; the study revealed that only 36% of patients with good compliance to diet have FBG less than 140 mg/dl.

Glycemic control is an important predictor for many of the chronic complications of diabetes¹⁴. Thirty eight percent of patients with good diet compliance had good HBA1c control (below 7%). Khattab et al reported in their study that the degree of control was found to have a significant relationship with the degree of compliance to diet³. Greenfield¹⁵ found that compliance was causally related to improvement in the diabetic controls, other studies have found that there is no constant relationship between diabetes compliance and glycaemic control.^{16,17}

Sixty percent of the study population has good compliance to drugs; Kamel et al found that 78.3% of a sample of diabetics has very good behavior regarded medication compliance¹². Females appear to be more compliant with drugs than males, as women tend to feel more anxious about their disease and its complications than men do. A study conducted in Hong Kong¹⁸ reported that the percentage of poor compliance was similar between the two sexes.

The current study revealed that good compliance with drugs was seen in the age group above 50 years, this could be explained by that older patients are more prone to have disease progression, this leads to an increased awareness of the illness and better modulation to comply with treatment, besides, older patients often have more help and monitoring from the family members.

About one third (29.8%) of the patients with good drug compliance had good FBS control, and 27.1 % of those with good drug compliance had good HBA1c. This poor glycemic control could be attributed to the fact that many patients believe that their disease is curable and so they stop taking their drugs as soon as symptomatic relieve is obtained. Rhee et al found in their study about type 2 DM in Georgia that taking medications would be associated with improved glycemic control.¹⁹

In respect to the compliance with visits; the current security condition in Iraq led to restriction of patients' movement, this may explain the low percentage of patients with good compliance to visits. We found that males had relatively better compliance with visits than females. Similarly Neal et al in their retrospective study reported that the likelihood of someone missing at least one appointment was independently associated with being a female and being a young adult.²⁰

Only twenty-six percent of those with good compliance with visits had good glycemic control. Those with irregular follow-up are more likely to have poor glycemic control. Rhee et al found in their study that diabetic patients in a managed care setting who missed more than 30% of their scheduled appointments within one year had A1C levels that were 0.7% higher than those who kept all appointments.¹⁹

We can conclude from this study that diabetic patients (represented by our sample) have poor compliance with diet and visits, the duration of the disease was the most common variable found to predict compliance. By improving the physician-patient communication, the self-monitoring

techniques, distributing health messages, education, motivation, and counseling through the mass media; patients' compliance can hopefully be improved.

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