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Adherence to Oral Antidiabetic Medications among Type 2 Diabetic (T2DM) Patients in Chronic Ambulatory Wards of Hiwot Fana Specialized University Hospital, Harar, Eastern Ethiopia: A Cross Sectional Study

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Abstract

Background: Diabetes mellitus (DM) refers to a group of common metabolic disorders that share the characteristic of hyperglycemia. It is associated with abnormalities in carbohydrate, fat, and protein metabolism and results in chronic complications including microvascular, macrovascular, and neuropathic disorders. Evidence indicates that it is the level of blood glucose, which the patients can achieve during their treatment, influences diabetic complications on the long run. Achievement of optimal blood sugar level is generally based appropriate utilization of existing oral antidiabetic drugs, proper adherence to prescribed regimens and patients' own managements of their illness. The study was, therefore, aimed to assess adherence to oral antidiabetic drugs among diabetic patients attending chronic ambulatory wards of Hiwot Fana Specialized University Hospital (HFSUH).

Methods: Hospital based cross-sectional study design was conducted in HFSUH from January 1-February 28, 2015 G.C. Convenience sampling technique was employed to select eligible diabetic patients during the study period. The data was collected by interviewing T2DM patients receiving antidiabetic medication and attending chronic ambulatory wards of HFSUH using structured questionnaire that includes Morisky four item adherence assessment method. The most recent fasting blood glucose (FBG) level was used for glycemic control. The collected data was processed and analyzed with SPSS version 16. Cross tabulation followed by Chi-square (χ^2) test was applied to show the association between categorical variables with adherence to antidiabetic medications.

Results: As per the Morisky's four item method of adherence, 40 (20.4%) patients reported that they were not being careful in taking their medication, 31 (15.8%) patients forgot to take medications regularly, only 3 (1.53%) patients stopped medication when they felt better and the other 5 (2.55%) patients reported that they stopped when they felt worse. From this finding, 138 (70.4%) patients adhered to the prescribed oral anti-diabetic medications. However, the remaining 58 (29.6%) T2DM patients replied positive response (yes) at least one of the four items and were classified as non-adherent to their medication. Educational status and residence showed a statistically significant association with adherence status (P<0.05). Moreover, a statistically significant association was also observed between adherences status and glycemic outcomes in the study (p<0.05).

Conclusion: the study showed that the level of adherence in T2DM patients was found to be suboptimal. The optimum blood glucose range might not be realized without proper adherence to the prescribed drug regimen. Therefore, patients should be advised on how to take their medication correctly and adequate information should be provided regarding the benefits of using them there by reducing both intentional and non-intentional non adherence.

Introduction

Diabetes mellitus (DM) refers to a group of common metabolic disorders that share the characteristic of hyperglycemia. World Health Organization (WHO) estimated that greater than 346 million people have DM at the global level. The present value is more likely to be doubled at 2030 provided that no immediate action is implemented on the near future. Low and middle-income countries are the most victimized areas that accounted for 80% of deaths due to DM. The chance of death in T2DM from cardiovascular complication is generally three times of the normal individuals [1,2].

In African, 80% of diabetic patients are undiagnosed. Data regarding the long term impact of DM is very limited in sub-Saharan Africa. However, along with significantly elevation of the disease, the incidence of complication has become noticeable indicating the significance of assessing the issue. There are a multitude of factors that contribute for DM management such as age, complexity of the regimen, chronicity of the disease, and psycho-social aspects [3-5]. The prevalence of DM in Ethiopia is estimated to be around 1.9% in adults [6].

A body of evidence indicated that the level of blood glucose, which the DM patients can achieve, determines the long term diabetic complications and the risk of morbidity and mortality. Rational use of antidiabetic medications is required to realize optimum blood glucose

level. Currently, combinational therapeutic approaches are preferred to monotherapy for better control of blood glucose level and hence reduce the risk of long term complications and mortality [7, 8]. Besides, optimum glycemic control can be achieved with patients' self-management of illness such as lifestyle modifications in addition to adherence to the prescribed regimen [9,10].

Meta-analysis of several studies revealed that the degree of adherence to oral medications ranges from 36% to 93%. Non-adherence to this medication may come from several contributing factors including, medication side effects, cost of therapy and poor patient-provider interaction [11]. Non adherence to their medication results in long term microvascular and macrovascular complications, increased length of hospital stay, elevated direct and indirect health care costs, among others [12].

In low income countries like Ethiopia where health care delivery and recourses are often scarce, there is high intention of assessing non adherence of DM patients towards their medication and probing the underlying causes for non-adherence [13]. Therefore, the present study was aimed to assess the adherence status and potential factors that likely affect adherence to oral antidiabetic medications among T2DM patients attending chronic ambulatory wards of HFSUH in the study period.

Methods

Study design and setting

Cross sectional study design was used to assess adherence to oral antidiabetic drugs, factors affecting adherence and glycemic outcomes among T2DM patients attending chronic ambulatory wards of HFSUH, Harar which is located 526 km away from the capital of Ethiopia, Addis Ababa to the east. The study was conducted from January 1 February 28, 2015.

Study population

All T2DM patients receiving oral antidiabetic medication in the ambulatory wards of HFSUH during the study period

- Ambulatory patients who are on oral anti-diabetic medications for greater than six months; patients who were consented to participate in the study and attended the diabetic clinic were included
- Patient aged less than 18 years; patients who were very ill, who were not willing to give information as well as psychiatric patients were excluded

Sample size determination and sampling techniques

All eligible T2DM patients who attended the chronic ambulatory wards of HFSUH during the study period were included. A convenience sampling technique was used to include eligible and voluntary patients at the time of data collection.

Data collection tool and procedure

Data was collected prospectively by interviewing T2DM patients receiving oral antidiabetic medication using structured questionnaire translated into the languages of residence (Afan Oromo and Amharic).

Variables

Independent variables: Socio-demographic factors including age, gender, religion, educational status, marital status, income and area of residence can affect adherence of DM patients. Other clinical characteristics (e.g. duration of disease since diagnosis, number of drugs being taken and co-morbid illnesses) may possibly affect the adherence.

Dependent variable: Adherence status of patients is a target variable to be affected by the aforementioned socio-demographic and clinical characteristics of patients. The serum glycemic level is also affected by the patients' state of adherence towards the prescribed medications.

Operational Definitions

Adherence is defined as the proportion of prescribed doses of medication actually taken by a patient over a specified period of time.

- Adherent is defined as at negative responses (No) to the four Morisky items (question asking about whether they forget, omit doses of their medication, stop when felt better or when felt worse)
- Non adherent defined as at least one positive response (yes) to any of the four items
- Fasting blood glucose is referred as blood glucose level of DM patients after overnight fasting (8 h or beyond)

Patients were divided into two groups according to the criteria established by the American Diabetic Association (ADA) [14]

- Good glycemic control - patients who have fasting blood glucose level (FBS) $\leq$ 126 mg/dl (7.0 mmol/l) and HbA1C $\leq$ 7.0%.
- Poor glycemic control - patients who have fasting blood glucose level (FBS)>126 mg/dl (7.0 mmol/l) and HbA1C>7 .0%.

Data processing and analysis

Data were entered and analyzed by using SPSS version [16]. The data were cross-tabulated followed by Pearson chi-square test for comparison of categorical variables. P value less than 0.05 was considered to be statistically significant.

Results

Socio-demographic characteristics

Amongst 200 T2DM patients attended in the study period, a total of 196 patients were interviewed with a response rate of 98%; 107(54.6%) were males and the rest 89 (45.4%) were females with the ratio of 1.2:1. Coming to age of the patient, 48.98% of participants were greater than sixty years, 47.4% of them were 41-60 years and the rest (3.6%) were b/n 18-40 years age group with the mean age of 61.11($\pm$ 11.72) years. Besides, 156 (79.6%) of the patients were married followed by widowed 20 (10.6%).

Coming to educational status, 117(59.7%) of them report that they were unable to read and write, 55 (28.1%) have primary while the rest have secondary and tertiary education with 12(6.1%) in each. Regarding to their social habits, 111 (56.6%) of them report that they were free of any social habits, 82 (41.8%) of them were khat chewers. A total of 165 (84.2%) have low or no monthly income i.e. less than 1000 ETB (Table 1).

Socio-demographic characteristics		frequency	%
Age	18-40	7	3.6
	41-60	93	47.4
	>60 years	96	48.98
	Total	196	100
Sex	Male	107	54.6
	female	89	45.4
	Total	196	100
Religion	Muslim	80	40.8
	Orthodox	82	41.8
	Protestant	32	16.3
	Other	2	----
	total	196	100
Ethnicity	Oromo	84	42
	Amhara	58	29.6
	Adare	25	12.8
	Gurage	14	7.1
	Other	15	7.7
	Total	196	100
Marital status	Single	2	-----
	Married	156	79.6
	Divorced	13	6.6
	Separated	5	2.6
	Widowed	20	10.6
	Total	196	100
Educational level	Unable to read and write	117	59.7
	Primary	55	28.1
	Secondary	12	6.1
	Tertiary	12	6.1
	Total	196	100
Residence	Urban	153	78.1
	Rural	43	21.9
	Total	196	100
Social habit	Smoker	2	----
	Alcoholics	1	----
	Chat chewer	82	41.8

	None	111	56.6
	Total	196	100
Monthly income	<1000 ETB (<45 USD)	165	84.2
	1001-5000 ETB (45-225 USD)	30	15.3
	>5000 ETB (>225 USD)	1	----
	Total	196	100
*ETB=Ethiopian birr; USD=US dollar			

Table 1: Frequency distribution of socio-demographic characteristics of T2DM patients in HFSUH, Harar, Ethiopia, Jan 1-Feb 28, 2015 (n=196).

Clinical characteristics of patients

Clinical characteristics of patients		frequency	%
Duration of DM since diagnosis (y)	≤ 5	107	54.6
	06-10	62	31.6
	>10	27	13.8
	total	196	100
Family history	Yes	14	7.1
	No	182	92.9
	Total	196	100
FBG	Good ($ 26 mg/dl /7.0 mmol/L)	76	38.8
	Poor(>126 mg/dl /7.0 mmol/L)	120	61.2
	Total	196	100
Co-morbidities	Yes	41	20.9
	hypertension	37	18.9
	Heart failure	1	0.5
	Other	3	1.5
	No	155	79.1
	Total	196	100
# Drugs	One	129	65.8
	Two	38	19.4
	Three	26	13.3
	Four	3	1.5
	Total	196	100
*FBG=fasting blood glucose; drugs are not exclusive to diabetic therapy.			

Table 2: Frequency distribution of clinical characteristics of T2DM patients in HFSUH, Harar, Ethiopia, Jan 1-Feb 28, 2015 (n=196).

The duration of diabetes since diagnosis indicates that 107 (54.6%) T2DM patients had been diagnosed for less than or equal to five year, 62 (31.6%) patients for 6 to 10 years, and 27 (13.8%) of them for greater than 10 years.

Besides, 182 (92.9%) patients have no family history of DM. Around 120 (61.2%) patients had poorly controlled their blood glucose level.

A total of 155 (79.1%) participants have no co morbidities, 41 (20.9%) patients were reported that they had co morbidities. The most commonly reported co-morbid condition was hypertension 37 (18.9%). Concerning the number of medications they were using, 129 (65.8%) of them were using one drug (monotherapy), 38 (19.4%) of them were using two drug and 26 (13.3%) of them have been using three drugs (Table 2).

Adherence status of patients

From the total of respondents, when asked about adherence to their medication as per the Morisky's four item method, 40 (20.4%) of patients reported that they were not being careful in taking their medication, 31 (15.8%) of them forgot to take the drugs, only 3 (1.53%) patients stopped medication when they felt better and the other 5 (2.55%) patients reported that they stop when they felt worse (Table 3). Concerning the overall adherence status, this study found that 138 (70.4%) of the respondents were adherent to their medication while 58 (29.6%) of them were not adherent (Figure 1).

Ser. No	Four adherence questions (item)	Yes (positive response)	%
1	Do you ever forget to take your ant diabetic medication (s)?	31	15.8
2	Do you sometimes, not being careful in taking your medication (s)?	40	20.4
3	When you feel better, do you sometimes stop taking your antidiabetic medication (s)?	3	1.53
4	Sometimes if you feel worse when you take your antidiabetic medication (s), do you stop taking them?	5	2.55
*multiple responses (rounding) is possible (summary of Morisky's four item method of adherence assessment).			

Table 3: Frequency distribution of response to adherence question among T2DM patients in ambulatory wards of HFSUH, Harar, Ethiopia, Jan 1-Feb 28, 2015 (n=196).

The adherence status of each patient was determined based on his/her response to the four adherence question. Patients who replied "yes" to one of four questions were categorized as non-adherent.
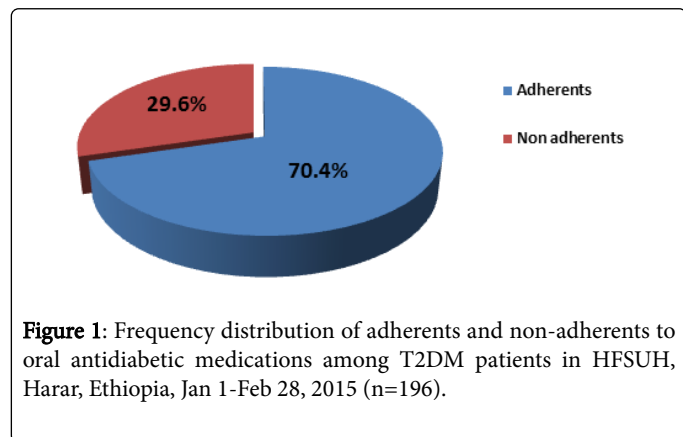

Figure 1: Frequency distribution of adherents and non-adherents to oral antidiabetic medications among T2DM patients in HFSUH, Harar, Ethiopia, Jan 1-Feb 28, 2015 (n=196).

From non-adherents, a total of 31 (53.45%) participants explained their reason for non-adherence towards their medication as forgetting, 23 (39.66%) of them replied for omission of doses due to various reasons as one cause of non-adherence. Other factors include lack of finances 11 (18.97%) and long duration of therapy in case of 5 patients (8.62%) (Table 4).

Factors	Frequency	%
Lack of financial resources	11	18.97
Long duration of treatment period	5	8.62
Forgetfulness	31	53.45
Decision to omit due to other reasons	23	39.66

*Omission might be due to side effects, poor patient-provider relationship etc. (multiple responses at times, overall percentage may exceed 100).

Table 4: Patients' opinions on factors that prevent optimal medication adherence among non- adherent type 2 DM patients in HFSUH, Harar, Ethiopia, Jan 1-Feb 28, 2015 (n=58).

Coming to association between socio-demographic variables and status of adherence to ant diabetic medications, statistically significance association was observed between adherence status with religion (p=0.044), education status (p=0.040) and area of residence (p=0.000). The association between place of residence and adherence status showed that patients from rural area were more non adherent with high level of significance (P=0.000) (Table 5).

Socio-demographic Variables	Category	Adherence status		P-value
		Adherent No (%)	Non-adherent No (%)	
Age	18-40	5 (3.62)	2 (3.44)	0.737
	41-60	63 (45.65)	30 (51..72)	
	>60	70 (50.72)	26 (44.83)	
	Total	138 (100)	58 (100)	
Gender	Male	77 (55.79)	30 (51.72)	0.601
	Female	61 (44.20)	28 (48.28)	
	Total	138 (100)	58 (100)	
Religion	Muslim	54 (39.13)	26 (44.83)	0.044*
	Orthodox	57 (41.30)	25 (43.10)	
	Protestant	27 (19.57)	5 (8.62)	
	Other	0 (0)	2 (3.44)	
	Total	138 (100)	58 (100)	
Ethnicity	Oromo	55 (39.86)	29 (50.0)	0.227
	Amhara	39 (28.26)	19 (32.76)	
	Adare	22 (15.94)	3 (5.17)	
	Gurage	10 (7.25)	4 (6.90)	
	Other	12 (8.69)	3 (5.17)	
	Total	138 (100)	58 (100)	

Marital status	Single	1 (0.72)	1 (1.72)	0.716
	Married	112 (81.16)	44 (75.86)	
	Divorced	10 (7.25)	375.86	
	Separated	3(2.17)	2 (3.44)	
	Widowed	12 (8.69)	8 (13.79)	
	Total	138 (100)	58 (100)	
Educational status	unable to read and write	79 (57.25)	38 (65.51)	0.040*
	Primary	40 (28.98)	15(25.86)	
	Secondary	9 (6.52)	3 (5.17)	
	Tertiary	10 (7.25)	2 (3.45)	
	Total	138 (100)	58 (100)	
Residence	urban	117 (84.87)	36 (62.07)	0.000*
	Rural	21 (15.21)	22 (37.93)	
	Total	138 (100)	58 (100)	
Monthly income	<500 ETB	114 (86.60)	51 (87.93)	0.571
	500-1000 ETB	23 (16.67)	7 (12.07)	
	>1000 ETB	1(0.72)	0 (0)	
	Total	138 (100)	58 (100)	
*Measurement of comparison was made by Pearson chi-square test, p value less 0.05 was considered to be statistically significant (n=196); ETB=Ethiopian birr.				

Table 5: Association between socio-demographic variables and adherence status among T2DM patients in HFSUH, Harar, Ethiopia, Jan 1-Feb 28, 2015(n=196).

The association between duration of DM since diagnosis and adherence status showed that those who diagnosed greater than five years were less adherent than those diagnosed for less than five years and the association was found to statistically significant (p=0.03). The relation b/n blood glucose levels and adherence status in this study indicated that from those who were non adherent to their medication, majority of them have poorly controlled blood glucose level compared to adherents and the association is highly significant (P=0.006) (Table 6).

Disscussion

Adherence to medication

This study generally emphasized on assessing the T2DM patients' self-reported adherence to their oral antidiabetic medication. Adherence rate to antidiabetic medications was found to be 70.4%. By the same token, among the T2DM patients, 29.6% patients were categorized as non-adherent to the prescribed regimen. Lower than this adherence rate was reported from different areas of the world such as 43.34% in southern India [15] 68.8% in Assela general hospital, Ethiopia, [16] 45% in Sudan [17] 66.8% in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia, [18] and 40.95% in southern Ethiopia [19]. In the contrary, better than the present value was also reported from various areas including 72.5% in eastern Nigeria [11] 83.3% in

eastern Uganda [20] 86.8 in Lagos, Nigeria [21] and 75.7% in Jimma University specialized hospital, southwest Ethiopia [22] This difference is partly ascribed to variation of socio-demographic and socio-economic characteristics as well as other contributing factors that can somehow affect optimal adherence in the aforementioned studies. Non-adherence to medications among diabetic patients might result in poor glycemic control.

The duration of living with diabetes since the time of diagnosis plays a significant role for their blood glucose control. This study found that T2DM patients with shorter duration of diabetes (≤ 5 years) (42.86%) were more adherent to their medication than those having diabetes for more than 5 years (27.55%). This shows that long duration of therapy influences adherence to their antidiabetic medications. Therefore, due to chronic nature of the disease, the likelihood of non-adherence is expected [23]. Adherence to the prescribed medication was positively linked with diabetes-specific -quality of life in patients [24].

Adherence and glycemic control

In this study, only 76 (38.78%) of the subjects had good glycemic control. It is also further supported by the study done in different settings where the adequate glycemic control was found to be 12.7%, 61.7%, 41.8% and 53.49% in Tikur Anbessa specialized hospital,[18] eastern Nigeria,[11] southern Ethiopia[19], and India health care setting [25], respectively. In this study, majority of the patients who

have adherence to their oral antidiabetic agents had decreased fasting plasma glucose even if it was not found appreciable. One study in black South African T2DM patients showed that antidiabetic medication adherence was positively correlated with a decline in glycated hemoglobin levels (HbA1c)[26]. Even though HbA1c level has been used as indicator of better glycemic control in many settings, the diagnosis was found inconsistent and incomplete in this hospital. Therefore, only the fasting blood glucose level (FBG) was subjected for association study with adherence.

Selected clinical characteristics		Adherence status			P value
		Adherent	Non-adherent	Total	
Glycemic outcomes	Good	62 (31.63)	14 (7.14)	76 (38.78)	0.006*
	Poor	76 (38.78)	44 (22.45)	120 (61.22)	
	Total	138 (70.41)	58 (29.60)	196 (100)	
Duration of DM since diagnosis	< 5 years	84 (42.86)	23 (11.73)	107 (54.59)	0.030*
	>5 years	54 (27.55)	35 (17.86)	89 (45.41)	
	Total	138 (70.4)	58 (29.6)	196 (100)	
Number of drugs	One	85 (43.37)	44 (22.44)	129 (65.82)	0.08
	Two	30 (15.31)	8 (4.08)	38 (19.38)	
	Three	21 (10.71)	5 (2.55)	26 (13.27)	
	Four	2(--)	1 (--)	3 (--)	
	Total	138 (70.41)	58 (29.60)	196 (100)	
*Chi-square test, P value less 0.05 was considered to be statistically significant (n=196).					

Table 6: Association between some clinical characteristics with adherence status of the T2DM patients, HFSUH, Harar, Ethiopia, Jan 1-Feb 28, 2015 (n=196).

Adherence and socio-demographic characteristics of patients

Coming to the socio-demographic characteristics, place of residence was significantly associated with adherence status and it seems to have significant influence on patient tendencies towards optimum adherence. A majority of urban DM patients were found to be adherent unlike that of rural residence where there was an even distribution of adherent and non-adherent patients. In this study, the chi-square analysis showed that place of residence is one of a determinant factor that affects the rate of adherence. This is because those in rural residences are more likely to give low attention to their medication, more distant from health care setting and are less likely to seek health information compared to urban residents. It was further supported by a study conducted in Egypt where rate of adherence was found to be 41.9% in urban and 34.4% in rural [1]. Moreover, being at higher education level also significantly increases the likelihood of adherence to antidiabetic medications. In other studies done at Assela general hospital, Ethiopia, among socio demographic factors, educational level and monthly income showed a significant association with adherence status [16]. What is more, younger age, degree of poly pharmacy and occupation were significantly associated with antidiabetic medication non-adherence in Tikur Anbessa specialized hospital, Addis Ababa [18].

Reasons for non-adherence

Factors leading to non-adherence in this study include forgetting to take their medication, omission of doses, lack of finances, and long duration of therapy in case of some DM patients. In research conducted at Addis Ababa Tikur Anbessa specialized hospital using four-item Morisky instrument, most of the patients missed their medications because of forgetfulness [18]. Generally, forgetfulness was one of the commonly mentioned reasons for non-adherence, which could be overcome by using different measures like informing family members to remind, and using alarm. Intentional omission of doses was the next factors. Patients omit the doses of their medication simply because the medication run out or they go elsewhere from home. The other common factors caused non adherence in this study was lack of finance. Even though oral antidiabetic medications are affordable and the hospital provides dugs for patients who cannot purchase by their own, still there were patients complaining this problem. Other studies, that are concordant to this study, also showed that the factors identified by patients as underpinning non-adherence were lack of finance and forgetfulness [27,28]. It was also further supported by a study conducted in India where the most common reasons for non-adherence were inadequate knowledge about therapy, financial problem, patients feeling better and feeling worse [29].

Conclusion

The study showed that the level of adherence in T2DM patients was found to be suboptimal. Carelessness and forgetfulness were reported to be the major factors for non-adherence to their medication. The optimum blood glucose range might not be realized without proper adherence to the prescribed drug regimen. Therefore, patients should be advised on how to take their medication correctly and adequate information should be provided regarding the benefits of using them

there by reducing both intentional and non-intentional non adherence on the long run.

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