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Non-adherence and Associated Factors among Type 2 Diabetic Patients at Jimma University Specialized Hospital, Southwest Ethiopia

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Treatment non-adherence for chronic illnesses such as diabetes is a common problem. The aim of the study was to assess the pattern of non-adherence to diabetic therapy and associated factors among type 2 diabetic patients. A cross sectional study was conducted from February 01 to April 30, 2011, at Jimma University Specialized Hospital diabetic clinic. Data on Socio-demographic characteristics, disease related and medication related factors, complexity of regimen and drug side effects were collected. Medication non-adherence was measured using a self-reported 4-item Morisky scale. Patient characteristics, number and dosing of all prescribed medications, glycemic control levels, diabetes related complications, co-morbid conditions and diabetes related admissions were reviewed from patient records. Univariate and multivariate logistic regression model was used to identify the factors related to non-adherence. Among the total of 267 type 2 diabetic patients (mean age 52.4±11.9), the prevalence of non-adherence was 24.3% (n = 267). About half of the patients 140 (52.4%) were on Metformin/Glibenclamide based combination therapy. Patients with depressive symptoms (AOR = 2.404, 95% CI = 1.323-4.366, p = 0.004) and who experienced side effects (AOR = 1.868, 95% CI = 1.012-3.446, p = 0.046) were twice more likely to be non adherent than without depressive symptoms and without manifesting side effects, respectively. Similarly, diabetic patients on complex regimen were three times non adherent (AOR = 3.413, 95% CI = 1.652-7.050, p = 0.001) than those with simple regimen. In conclusion, non-adherence in the current study was high particularly among patients with depressive symptoms, side effects and on complex regimen. Thus, continuous adherence monitoring and support services need to be implemented to such group of patients.

Key words: Type 2 diabetes, drug therapy, non-adherence, depressive symptoms, side effects, complex and regimen

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INTRODUCTION

The burden of diabetes mellitus has emerged as one of the rapidly increasing non-communicable diseases and a major public health challenge in developing countries like Ethiopia (Worku *et al.*, 2010). This could be attributed in part to ageing population, urbanization, western style diet, increasing obesity, poor education and markers of poverty and sedentary lifestyles (WHO, 2003a; Fekadu *et al.*, 2010). Though national data regarding the prevalence of diabetes in Ethiopia are non-existent, diabetic cases were estimated to about 800,000 by the year 2000 and projections for the number of people with diabetes (within 20-79 age group) show that some 2.6 million people are expected to have diabetes in Ethiopia by the year 2025 (Whiting *et al.*, 2011; WHO, 2003b). The number may outstrip beyond this as access to care, as a major problem in Ethiopia, may contribute to poor prognosis for people with diabetes (Alemu and Watkins, 2004). Patients have to travel long distances to the nearest medical center in order to get medical care and medications. In addition, high cost of medications and overall medical cost remains a very serious problem (Feleke and Enquselassie, 2005).

The prevalence of non-adherence to treatment recommendations for chronic illnesses such as diabetes is a common problem in every practice (Delamater, 2006) and has been reported to range from 20 to 60% (Bosworth 2010). Twenty eight percent of diabetic patients from an urban primary care clinic of New York City (Mann *et al.*, 2009), 28.9% in Uganda (Kalyango *et al.*, 2008), 59% in Nigeria (Yusuff *et al.*, 2008) and 21.7% in Southern Brazil (Gimenes *et al.*, 2009) and 39% in Egypt (Shams and Barakat, 2010) were reported to be non-adherent to their anti-diabetic drug therapy. Similarly, problems of non adherence to diabetic medications (17%), dietary advice (62%) and physical activity recommendations (47%) have also been detected by Moreau *et al.* (2009). Diabetic medication non-adherence has also been shown to cause considerable morbidity, mortality, substantial worsening of disease, increased rates of hospital admissions, physician office visits, use of expensive medical resources, unnecessary change of medications, unexplained treatment failures and increased direct and indirect costs (Kocurek, 2009).

Some studies have attempted to document, with varying degree, factors to diabetes non-adherence (Delamater, 2006; Yusuff *et al.*, 2008; Adisa *et al.*, 2009; Kocurek 2009; Moreau *et al.* (2009). Previous studies conducted at the diabetic clinic of Jimma University Specialized Hospital, demonstrated that 47% of patient had poor glycemic control and many patients developed diabetes related complications (Kelemu, 2006; Worku *et al.*, 2010). However, the spectrum of non-adherence and its associated factors in Ethiopian setup

have not been investigated before. Thus, the aim of the present study was to assess the level of diabetic non-adherence and the spectrum of associated factors and the relationship of medication non-adherence and diabetic outcomes in Ethiopian tertiary health care setup.

MATERIALS AND METHODS

Study design: A cross sectional study was conducted at the diabetic clinic of Jimma University Specialized Hospital (JUSH), Jimma town, Southwest Ethiopia from February 01 to April 30, 2011. JUSH is a tertiary level teaching hospital providing comprehensive health care service in southwest of Ethiopia. There are 2800 patients on follow-up for diabetes care in the hospital, out of which, 60% (1700) were diagnosed with type 2 diabetes mellitus.

Study participants: The source population comprised all type 2 diabetic patients attending Jimma University hospital for follow up. Eligible study participants were patients on follow up for at least 90 days and age =18 years. All type 1 diabetic patients, pregnant patients and acutely ill and mentally impaired patients were excluded out of the study. The sample size required for the study was determined using the formula for single population proportion by considering the prevalence rate of non-adherence 29% (Kalyango *et al.*, 2008) and 5% margin of error at 95% confidence interval and finally adjusting for finite population correction. Systematic random sampling (sampling interval (k) of $N/n (1700/267 = 6)$) was used to enroll participants from the study population.

Methods: For all included patients socio-demographic characteristics (age, sex, marital status, educational status, income, distance from the clinic, family support and habits of smoking, chat chewing and alcohol drinking habit), non adherence level, patient belief about diabetes medications, patient-provider relationship, disease related factors (history of depressive symptoms, co-morbidities, duration of diabetes treatment and duration since last visit) and medication related factors (number of drugs, complexity of regimen and drug side effects) were collected through face to face patient interview. Simultaneously, patient records were reviewed for patient characteristics, number and dosing of all prescribed medications, glycemic control levels, diabetes related complications, co-morbid conditions and diabetes related admissions.

Study parameters and definitions

Medication non adherence: Medication non-adherence was measured using the self-reported 4-item Morisky scale (Morisky *et al.*, 1986; Rigby, 2007; Shi *et al.*, 2010)

which assesses patients' forgetfulness about taking medications, carelessness about taking medications, stopping medication when feeling better and stopping medication when feeling worse. Questions were answered as 'yes' and 'no' and scored one point for 'yes' and zero point for a 'no' response. Scores were summed to give total score, ranging from 0 to 4. Non-adherence was defined as a score greater than zero.

Glycemic control: Glycemic control was assessed using Fasting Blood Glucose (FBG) level. Last four readings of FBG were recorded from patients' records. FBG of 70 to 130 mg dL⁻¹ was classified as controlled and FBG >130 uncontrolled glycemic level. FBG level of <70 was considered as hypoglycemic risk (American Diabetes Association, 2010).

Complexity of regimen: The overall number of medications a diabetic patient was taking to treat diabetes and diabetes related complications and co-morbidities were assessed. A drug regimen was considered complex if a patient was taking ≥2 drugs with daily dosing of twice or more each (Park *et al.*, 2010; Shams and Barakat, 2010).

Patient belief about diabetic medications: Patients' belief and insight to anti-diabetic medicines was assessed based on the Beliefs about Medicines Questionnaire (BMQ) (Horne *et al.*, 1999).

Depressive symptoms: Depressive symptoms were assessed using the Patient Health Questionnaire (PHQ), a (Kroenke *et al.*, 2001) which assesses patient emotional symptoms of bothering, feeling depressed or hopeless, loss of interest or pleasure in doing things, trouble in sleeping, problem in eating, feeling tired or loss of energy, feeling bad and trouble in concentrating.

Ethical consideration: The study was conducted after ethical clearance was obtained from the Ethical Review Board (IRB) of College of Public Health and Medical Sciences, Jimma University (Ref. No.: RPGC/170/2011). Permission was obtained from Clinical Director of Jimma University Specialized Hospital to carry out the study in the diabetic clinic.

Statistical analysis: Descriptive statistics was computed to describe the socio-demographic profile of participants and the pattern of diabetic medication non adherence. Differences between non adherent and adherent characteristics were first explored by chi-square tests. Univariate and multivariate binary logistic regression model was carried out to identify the independent factors related to non-adherence. Backward elimination

(likelihood ratio) was as used as the variables selection method. Estimates of the risk factors were expressed as crude and adjusted Odds Ratios (OR) with 95% Confidence Intervals (CI). The data was analyzed using SPSS for windows, version 16.0 statistical software and P value<0.05 was considered significant for all analysis.

RESULTS

A total of 267 type 2 diabetic patients comprising 148 (55.4%) males and 119 (44.6%) females were included in this study. Majority of the participants were in the age range of 31-59 years (67%) (Mean age 52.4±11.9) and married 230(86.1%). The monthly income of 66.6% of the patients was below 500 Ethiopian Birr (Table 1). The patients' disease and medication related information revealed that most of the patients, 256 (94.7%) had been on diabetes treatment for at least one year. About half, of the patients were co morbid, 144 (53.9%) and on combination therapy containing Metformin and Glibenclamide 140 (52.4%). Larger proportions of patients, 175 (65.5%) were on complex regimen and the mean

Table 1: Socio-demographic characteristics of type 2 diabetic patients at the diabetic clinic of JUSH, Feb-Apr, 2011 (N = 267)

Socio-demographic characteristics	Frequency	%
Age range (years)		
18-30	11	4.2
31-59	179	67.0
≥60	77	28.8
Sex		
Male	148	55.4
Female	119	44.6
Total	267	100.0
Marital status		
Married	230	86.1
Widowed	22	8.2
Divorced	10	3.8
Single	5	1.9
Educational status		
Illiterate	72	27.0
Primary	104	39.0
Secondary	48	18.0
Tertiary	43	16.0
Monthly income (Et.Birr)		
<500	178	66.6
500-2000	72	27.0
>2000	17	6.4
Family support		
Yes	110	41.2
No	157	58.8
Distance from the clinic (Km)		
<6	134	50.1
6-24	45	16.9
>24	88	33.0
Habits of smoking		
Yes	1	-
No	266	99.6
Habits of chat chewing		
Yes	17	6.4
No	250	93.6
Habits of alcohol drink		
Yes	7	2.6
No	260	97.4

Table 2: Distribution of patient, disease, and medication related variables among type 2 diabetic patients at the diabetic clinic of JUSH, Feb-Apr, 2011, 2011 (n = 267)

Variables	Frequency	%
Belief to medications		
Good	221	82.8
Moderate	43	16.1
Weak	3	1.1
Patient-pr ovider relationship		
Good	244	91.4
Moderate	21	7.9
Weak	2	-
Depressive symptoms		
Yes	88	33.0
No	179	67.0
Side effects		
Yes	81	30.3
No	186	69.7
Duration of diabetes Rx (yrs)		
<1	14	5.3
1-5	136	50.9
>5	117	43.8
Duration since last visit		
1 month	75	28.1
2 months	165	61.8
3 months	27	10.1
Diabetes related hospitalization		
Yes	49	18.4
No	218	81.6
Type of diabetic medications		
One oral hypoglycemic	90	14.0
Combination oral hypoglycemic	33.7	52.4
Insulin containing combination	37	13.9
Complexity of regimen		
Simple	92	34.5
Complex	175	65.5
Co-morbidities		
Yes	144	53.9
No	123	46.1
Diabetes complications		
Yes	192	71.9
No	75	28.1
Average Fasting blood glucose (mg dL⁻¹)		
<70	2	-
70-130	94	35.3
>130	171	64.0

number of medications per patient was 2.71±1.14. At least one side effect to diabetic medications had been reported by 81 (30.3%) of participants. Significant proportions, 192 (71.9%) of the patients had developed at least one diabetes related complications and 49 (18.4%) of the patients had diabetes related hospital admission during the course of their treatment. In addition, the mean fasting blood glucose level was found to be 163±64.60 mg dL⁻¹. Sixty four percent (171) of patients had uncontrolled (FBG >130 mg dL⁻¹) blood glucose (Table 2).

The prevalence of non-adherence was 24.3% (n = 267). Univariate logistic regression model analysis revealed that presence of depressive symptoms (COR = 2.528, 95% CI 1.422-4.496, p = 0.002); side effects (COR = 1.947, 95% CI = 1.087-3.490, p = 0.025); complex regimen (COR = 3.286, 95% CI = 1.621-6.663, p = 0.001); diabetes related hospitalization (COR = 2.966, 95% CI = 1.540-5.712, p = 0.001); presence of diabetes complication (COR = 2.609, 95% CI = 1.250-5.445, p = 0.011) and Fasting Blood Glucose (FBG)(COR = 2.115, 95% CI = 1.111-4.027, p = 0.023) were significantly associated with non-adherence (Table 3).

Patients with depressive symptoms were about two fold more likely to be non adherent than without depressive symptoms (AOR = 2.404, 95% CI = 1.323-4.366, p = 0.004). Patients who experienced side effects to their medication were nearly twice more likely to be non adherent than those without manifesting side effects (AOR = 1.868, 95% CI = 1.012-3.446, p = 0.046). Similarly, diabetic patients on complex regimen were three times non adherent (AOR = 3.413, 95% CI = 1.652-7.050, p = 0.001) than those with simple regimen. Moreover, diabetic medication non adherence was twice more likely to result in diabetes related hospitalization (AOR = 2.420, 95% CI = 1.174-4.992, p = 0.017) than without diabetes related hospitalizations (Table 3).

Table 3: Factors associated with non-adherence among type 2 diabetic patients at the diabetic clinic of JUSH, April, 2011

Variables	Crude Odds Ratio (95% C.I)	Adjusted Odds Ratio (95% C.I)
Depressive symptoms		
Yes	2.528 (1.422-4.496, p = 0.002*)	2.404(1.323-4.366, p = 0.004*)
No	1.00	
Side effects		
Yes	1.947 (1.087-3.490, p = 0.025)	1.868(1.012-3.446, p = 0.046*)
No	1.00	
Complexity of regimen		
Complex	3.286 (1.621-6.663, p = 0.001*)	3.413(1.652-7.050, p = 0.001*)
Simple	1.00	
Diabetes complications		
Yes	2.609 (1.250-5.445, p = 0.011*)	1.569(0.701-3.512, p = 0.273)
No	1.00	
Fasting blood glucose		
70-130	1.00	1.469 (0.732-2.949, p = 0.280)
>130	2.115 (1.111-4.027, p = 0.023*)	
Hospitalization		
Yes	2.966 (1.540-5.712, 0.001*)	2.420(1.174-4.992,p = 0.017*)
No	1.00	

*Statistically significant association

DISCUSSION

In the current study, among type 2 diabetic patients investigated, 24.3% were non-adherent associated with depressive symptoms, side effects and complexity of regimen. Though non-adherence and diabetic outcomes (status of glycemic control, diabetes related complication and hospitalization) were studied at the same time and the study does not reveal cause-effect relationship, results of this study implicate that non-adherence may be associated with poor diabetic outcomes and could account for substantial worsening of diabetes, increased rates of hospital admissions and increased overall health care costs in diabetes patients.

A self reported, 4-item Morisky medication adherence scale was used to assess medication non-adherence. The patients were required to answer the questions on the basis of their adherence behavior since the previous visit. The time between visits might be longer where patients may fail to remember everything about their medication taking behaviors. However, self reported adherence measure correlates well with sub optimal adherence as measured by electronic medication monitors and pill counts (Shi *et al.*, 2010). Particularly this is considered the best method for routine practice if supported by assessment of the patient's clinical and laboratory response.

Although, measurement of glycosylated hemoglobin (HbA1c) is the standard method for assessing long term glycemic control in diabetes, it was found that none of the patients had their HbA1c value determined and unavailable on the patient medical record. Consequently, fasting blood glucose was used to assess levels of glycemic control. Factors related to habits of smoking, chat chewing, alcohol use, patient belief to medication, patient provider relationship and number of medication, though they might have roles to impact non adherence, were excluded from the analysis because this variables did not fulfill the chi-square assumptions.

Medication non-adherence is a considerable problem in the management of patients with chronic diseases such as diabetes. Reports show that the prevalence of treatment non-adherence for chronic illnesses such as diabetes generally ranges from 20 to 60% (Bosworth, 2010). The extent of non-adherence (24.3%) found in the current study was lower compared to the results of other studies reported (Kalyango *et al.*, 2008; Yusuff *et al.*, 2008). However, non-adherence rate in the present study was found to be higher in comparison with the reports of other studies (Howteerakul *et al.*, 2007; Gimenes *et al.*, 2009; Moreau *et al.* (2009). Higher rate of side effects were reported by Yusuff *et al.* (2008) (hypoglycemia in 60.3%) and was the most common factor for non-adherence. This was not the case in this study. The discrepancy could be

attributed to the difference in metrics to assess medication non-adherence and/or differences in health care setting and socio-economic status or difference in reported perceived reasons for non-adherence.

Practitioners should be cognizant of medication side effects and how this may affect long-term efforts to successfully management of diabetes mellitus. Early identification and management of medication related tolerability issue is important to achieve positive diabetes outcomes. It was revealed in this study that patients who experienced side effects to their medication were two times more likely to be non-adherent as compared to patients without side effects. Other studies are also consistent with this finding (Mann *et al.*, 2009; Pollack *et al.*, 2010; Shams and Barakat, 2010). The most common side effects reported in the current study were GI side effects (13.9%) and hypoglycemic symptoms (13.1%). Higher prevalence of side effects was reported from other report including symptoms of hypoglycemia (57.2%), constipation/diarrhea (28%), headaches (25.6%), weight gain (22.9%) and water retention (21.0%) (Pollack *et al.*, 2010). Lack of practice with self-monitoring of blood glucose in this study participants and hence unrecognized hypoglycemic signs and other symptoms might contribute for the lower rates of side effects in our study. This can also substantiated by the higher proportion (64.0%) of patients who had uncontrolled blood glucose (FBG >130 mg dL⁻¹) as demonstrated in this study.

Though patients with diabetes rarely receive treatments for psychological problems, the current study revealed that depressive symptoms were strongly associated with medication non-adherence and depressed patients were about three times more likely to be non-adherent than patients without depressive symptoms. This finding is in agreement with a study reported by Moreau *et al.* (2009). Psychological problems (including stress and depression) were also reported to affect treatment adherence in patients with type 2 diabetes (Rubin 2005; Dirmaier *et al.*, 2010). It is imperative that clinicians should recognize that depression and diabetes related emotional distress (frustration with symptoms and disease management) may lead to poor adherence hence negative clinical outcomes. Hence, identifying and treating depression and diabetes-related emotional distress can contribute to improved treatment adherence hence, positive treatment outcomes.

In addition to their anti-diabetic medications, diabetic patients have to take many medications to treat diabetes related complications and co-morbidities. Our finding demonstrated that patients on complex and multiple medications were non-adherent as compared to patients on one medication. The report of Shams and Barakat (2010) indicated that patients on complex drug regimens

were associated with lower adherence rate ($p < 0.05$). There were significant linear trends of poorer adherence with each increase in the daily number of tablets taken ($p = 0.001$) and increase in co-medication ($p = 0.001$) (Donnan *et al.*, 2002).

Results of the present study showed that non-adherent patients were associated with presence of diabetes complication, uncontrolled diabetes and increased hospital admission. Previous investigations have also showed similar findings. Patients with type 2 diabetes who do not obtain at least 80% of their oral anti-hyperglycemic medications across 1 year were at a higher risk of hospitalization in the following year (OR 2.53; 95% CI 1.38-4.64) (Lau and Nau 2004). Similarly, non-adherent patients had higher glycosylated hemoglobin and medication non-adherence was significantly associated with increased risks for all cause hospitalization (OR, 1.58; 95% CI, 1.38-1.81; $p < .001$) and for all-cause mortality (OR, 1.81; 95% CI, 1.46-2.23; $p < .001$) (Ho *et al.*, 2006). All these findings evidently indicate that poor adherence to antidiabetic medications pose a significant barrier to attain positive clinical or therapeutic outcomes among type 2 diabetic patients.

CONCLUSION

In conclusion, the prevalence of non-adherence to diabetic medications among type 2 diabetic patients was high particularly among patients with depressive symptoms, side effects and on complex regimen. Non-adherent patients appear to be at high risk of poor diabetic outcomes associated with occurrence of complications, increased hospitalization and uncontrolled fasting blood glucose. Thus, the present work signals a need for continuous intensive adherence monitoring, support and consultations service for type 2 diabetic patients particularly with depressive symptoms, side effects, complex and multiple medications and poor diabetic outcomes.

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