

Adherence to Treatment in Patients with Type 2 Diabetes Mellitus

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ABSTRACT

BACKGROUND: Adherence to medications is an important factor in effective prevention of diabetes complications. Assessment of treatment adherence is necessary for the effective treatment planning. This study was undertaken with the objective of assessing adherence to diabetes medications, association between adherence & glycemic control and factors affecting the poor adherence among the Type 2 DM patients. **METHODOLOGY:** A total of 236 diabetic patients were included in this cross sectional study. The required sample was obtained by simple random sampling from line listing of diabetic cases in the study area. Patients above the age of 18 years diagnosed with type 2 DM & on regular treatment for at least one year were included in the study. Glycemic control was assessed by the measuring glycated hemoglobin (A1C) value. **RESULTS:** The overall prevalence of poor adherence to diabetic medications i.e. brief medication adherence score ≥ 1 among the participants was 58.89%. There was a significant association between poor diabetic medication adherence level and their glycemic status. The majority of nonadherent patients (62.58%) had poor glycemic control state as compared to adherent patients (37.42%). Although female, frequent change in drug regimen, higher annual direct cost expenditure had higher percentages of poor medication adherence, none of these variables significantly related to poor medication adherence. However, it was found that education ≤ 10 years of schooling , duration of disease ≥ 5 years , frequency of dosing thrice daily and presence of other co-morbidities were significantly related to a low adherence level. **CONCLUSION:** A high percentage of the study population was poorly adherent to the diabetic medication. A more concerning fact was the significant association of the non-compliance with poor glycemic control, which emphasized the role of a repeated patient education regarding drug adherence.

Key Words: Adherence, diabetes, glycemic control, Salem

INTRODUCTION

Diabetes prevalence is rapidly increasing and it requires lifelong treatment with medications, regular health care follow-up for surveillance and prevention of complications, and ongoing lifestyle counseling. The majority of patients with type 2 diabetes fail to control glycaemia with diet and exercise and require pharmacotherapy—in general, initially monotherapy with an oral hypoglycemic agents (OHA); however, owing to the progressive nature of the disease, most of the patients will eventually require combination therapy and ultimately injectable treatments as monotherapy or part of polytherapy.

Despite the extensive therapy options available for various stages of type 2 diabetes, studies have indicated that less than 50% of patients achieve the glycemic goals recommended and approximately two-thirds die prematurely of cardiovascular disease. ⁽¹⁾Drugs and lifestyle changes to control type 2 diabetes and associated conditions can only be effective through adherence to the overall prescribed regimen. The World Health Organization (WHO) has shown that adherence to long-

term therapy for chronic illnesses in developed countries averages only around 50%. Such reduced adherence not only results in poor health outcomes but it also has a significant impact on healthcare costs. ⁽²⁾ The control of diabetes requires more than just taking medicine. Other aspects of self-management such as self-monitoring of blood glucose, dietary restrictions, regular foot care and ophthalmic examinations have all been shown to markedly reduce the incidence and progression of complications of diabetes.

Patients with diabetes usually have co-morbidities that make their treatment regimens even more complex. In particular, other commonly associated diseases such as hypertension, obesity and hypercholesterolemia are themselves known to be characterized by poor rates of adherence, and serve to further increase the likelihood of poor treatment outcomes. ⁽²⁾

Treatment adherence can be defined as the extent to which the patients take medications as prescribed by health care providers and as agreed upon in the patient's

treatment plan. ⁽³⁾ Adherence to medications is an important factor in effective prevention of diabetes complications. Poor medication adherence in patients with diabetes has been associated with increased health care resource utilization, increased all-cause mortality, and increased all-cause hospitalization rates. ⁽²⁾ Assessment of treatment adherence is necessary for the effective treatment planning. Methods of measuring adherence can be either direct (biological marker), which is more sensitive but can be invasive and is not usually practical, or indirect (self-reporting, questionnaires, pill counts). Number of studies has been published in India about non-adherence to medication in Type 2 DM, however it is essential to evaluate adherence on a regular basis due to changes in culture and life style.

This study was undertaken with the objective of assessing adherence to diabetes medications, association between adherence & glycemic control and factors affecting the poor adherence among the Type 2 DM patients.

METHODOLOGY

The cross sectional study was conducted to estimate poor medication adherence rate in type 2 diabetes mellitus patients in the urban field practicing area of our medical college hospital for a period of three months from August 2017 to October 2017. . Using a prevalence of 30 percent anticipated drug adherence and absolute precision of 6 percent with 95 percent confidence; the required sample size was estimated to be 232. The required sample was obtained by simple random sampling from line listing of diabetic cases in the study area. A separate information sheet was prepared for the data collection procedures. Informed consent was obtained from the participants. Confidentiality was maintained in the process of data collection. A total of 236 diabetic patients attending urban health centre and various private clinics & hospitals were enrolled for the study. Patients above the age of 18 years diagnosed with type 2 DM & on regular treatment for at least one year were included in the study. Exclusion criteria were being pregnant, older than age 75 years, or having other diseases that could significantly affect the analysis of resource use.

Data collection was done by house visit, using the structured questionnaire. The questionnaire was pilot tested for data quality and the questions were modified and finalized based on the results of the pilot study. The three sections of the questionnaire were (1) questionnaire based survey for socio demographic characteristics (2) the brief medication adherence questionnaire, (3) costs associated with diabetic care.

Glycemic control was assessed by the measuring glycated hemoglobin (A1C) value. The cut-off for optimal glycemic control in the present study was accepted at $HbA1C \leq 7\%$.

The Brief Medication Questionnaire explores both patient's medication-taking behavior and barriers to adherence. The tool includes

(1) A 5-item Regimen Screen that asks the patients about their medications that they were currently taking. Questions are asked to list the name of each medication, frequency of medication per day, number of days and times they have received each medication along with the number of times the patient missed taking medications in the past week,

(2) A 2-item Belief Screen consists of two questions that ask the patients whether they had any difficulty with any of the medications, and does the medication bother them in any way,

(3) A 2-item Recall Screen assesses the patient's difficulty in recalling and remembering the dosage regimen of their medications.

Direct costs were estimated using a bottom-up approach for primary data collection and divided into medical and nonmedical costs. The direct medical costs assessed included medications, procedures, medical supplies (such as blood glucose test strips), visits with physicians, and hospital costs for emergency room visits (including provider fees only). The direct nonmedical costs assessed included expenses with artificial sweeteners and diet products, and laboratory testing. Annual direct cost associated with diabetic care was divided into 2 based on the median value.

Insufficient physical activity: Insufficient physical activity can be defined as less than 5 times 30 minutes of moderate activity per week, or less than 3 times 20 minutes of vigorous activity per week. Examples of moderate intensity physical activity includes walking briskly, gardening, dancing, swimming, bicycling, volleyball, scrubbing floors, carrying water from river or well, manual grinding or pounding of cereals, manual washing of clothes. Vigorous intensity activity includes jogging, running, high impact aerobic exercise, rowing, carrying or lifting heavy loads, digging or construction work, football and cycling uphill.

Statistical Analysis: Descriptive statistics were used to describe demographic and clinical characteristics of the patients and their medication adherence levels. Poor adherence to medication was considered as brief medication adherence score ≥ 1 . Due to the skewed distribution of the cost associated with diabetic care, the median values and ranges are reported. χ^2 test was used to analyze the association between the predictor variables and poor adherence in bivariate analysis.

RESULTS

A total of 236 subjects were included in the study. The mean age of the sample population was 52.4 ± 9.8 . Females constituted 54.66%. Table 1 shows the characteristics of the study population. The percentage of respondents with more than 10 years of schooling was 27.12%. Participants were classified into sedentary, moderate and heavy based on their occupational

activities. Majority of the study population i.e. 63.13% (149) were having sedentary type of life style. This was followed by unemployed/retired i.e. 56 (26.73%) and moderate which had only 27(11.44%). Among women, home-makers comprised the highest percentage of those engaged in unpaid work. . Majority of the study population belonged to the lower middle (36.86%) followed by upper middle class (26.73%). The proportion of respondents consumed alcohol in the past 12 months was 11.02%. The total physical activity of the respondents is classified under two categories sufficient and insufficient on the basis of duration for which they perform physical activities of varying intensity. The level of physical activity was insufficient among 44.45% of the respondents. The mean duration of disease was (Mean ± SD) 5.8 ± 3.8. Majority of the patients were on oral hypoglycemic agent's i.e.78.81%.

Table 1: Characteristics of the study population (N=236)

Characteristics	Total n (%)	
Age in years (Mean ± SD)	52.4 ± 9.8	
Gender	Male	107 (45.34)
	Female	129 (54.66)
Education (years of schooling)	≤ 10	172(72.88)
	> 10	64 (27.12)
Occupation	Sedentary	149(63.13)
	Moderate	27 (11.44)
	Heavy	4 (1.70)
	Unemployed/ Retired	56 (23.73)
Socio economic status	Upper class	35 (14.83)
	Upper middle	56 (23.73)
	Lower middle	87(36.86)
	Upper lower	44 (18.64)
	Lower	14 (5.94)
Type of medication	OHA	186 (78.81)
	Insulin	9 (4.83)
Alcohol use	Both	41 (17.37)
		26 (11.02)
Physical inactivity	105 (44.45)	
Duration of disease (Mean ± SD)		5.8 ± 3.8
	Hypertension	126 (53.38)
Presence of other Co-morbidities	Hypercholesterolemia	78 (33.50)
	Heart disease	34 (14.40)

Among the study participants, 53.38% had hypertension and 33.50 % had hypercholesterolemia. The median annual direct cost (Rupees) associated with diabetic care was INR 8450.While calculating median direct cost associated with diabetic care, those who were seeking care in urban health centre& Govt. hospitals (27.96%) were excluded as medicines & care were provided free of cost.

The overall prevalence of poor adherence to diabetic medications i.e. brief medication adherence score ≥ 1

among the participants was 58.89%.Table 2shows the responses of the participants for the Brief Medication Adherence Questionnaire .The mean score of the study participants as 2.11± 0.81. 32.62% of the respondents reported missed days or doses of drug intake while 23.73 % of the respondents stop or interrupt therapy due to late refill or any other reason. 22 (9.3%) number of respondents name the prescribed drug as a drug that bothers him/her.The mean HbA1c in the study participants was 8.9± 1.82

Table 2 Responses for the Brief Medication Adherence Questionnaire

BMQ item	N (%)
No. of respondents failed to list the prescribed drug in the initial report	34(14.41)
No. of respondents stop or interrupt therapy due to late refill or any other reason	56(23.73)
No. of respondents report any missed days or doses	77(32.62)
No. of respondents reduce or cut down the prescribed amount per dose	24(10.17)
No. of respondents take any extra dose or more medication than prescribed	12(5.08)
No. of respondents report don't know in response to any Questions	18(7.63)
No. of respondents refuse to answer any questions	8(3.41)
No. of respondents name the prescribed drug as a drug that bothers him/her	22(9.32)

Table 3 Association between poor diabetic medication adherence and glycemic status

Glycemic status	N (%)	Poor adherence n (%)	OR (95% CI)	P value
HbA1c >7%	125(52.96)	87(62.58)	2.59(1	0.0003
HbA1C<7%	111(47.04)	52(37.42)	.52-4.42)	
Total	236(100.00)	139(100.00)		

Association between poor diabetic medication adherence and glycemic status: Table 3 shows the association between poor diabetic medication adherence and glycemic status. There was a significant association between poor diabetic medication adherence level and their glycemic status. The majority of poor-adherent patients (62.58%) had poor glycemic control state as compared to adherent patients (37.42%) (P-value0.0003). The mean HbA1c among poor adherent patients as 9.7±2.4, while mean HbA1c among adherent patients was 7.1± 0.8.

Factors Associated With Poor Diabetes Adherence: Table 4 shows the factors associated with poor diabetes medication adherence. Although female, frequent change

in drug regimen, higher annual direct cost expenditure had higher percentages of poor medication adherence, none of these variables significantly related to poor medication adherence in the chi-square test ($p > 0.05$). However, it was found that education ≤ 10 years of schooling (OR =2.14; 95% CI 1.19-3.83), duration of disease ≥ 5 years (OR 2.21; 95%CI 1.30-3.76), frequency of dosing thrice daily (OR 4.06; 95% CI 1.62-1016) and presence of other co-morbidities (OR 3.78; 95% CI 1.37-2.33) were significantly related to a low adherence level.

Table 4. Factors Associated With Poor Diabetes Medication Adherence

Variables	N (%)	Poor adherence N (%)	OR (95% CI)	P value	
1. Gender	Female	129 (54.66)	79 (56.83)	1.23(0.7-3.2.08)	0.42
	Male	107 (45.34)	60 (43.17)		
2. Education (years of schooling)	≤ 10	172 (72.88)	110 (79.13)	2.14(1.1-9-3.83)	0.009
	> 10	64 (27.12)	29 (20.87)		
3. Duration of disease (years)	≥ 5	127 (53.81)	86 (61.87)	2.21(1.3-0-3.76)	0.002
	< 5	109 (48.18)	53 (38.13)		
4. Frequent change in treatment regimen	Yes	94 (39.83)	57 (41.00)	1.1 (0.66-1.91)	0.65
	No	142 (60.17)	82 (59.00)		
	Thrice daily	88 (37.28)	59 (42.44)		
5. Frequency of dosing	Twice daily	121 (51.27)	71 (51.07)	2.84(1.8-1-6.83)	0.001
	Once daily	27 (11.44)	9 (6.47)		
6. Presence of other co-morbidities	Yes	141 (59.74)	101 (72.66)	3.78(1.3-7-2.33)	0.001
	No	95 (40.26)	38 (27.34)		
7. Annual direct cost (Rupees) associated with diabetic care N=170	≥ 8450	83 (48.82)	54 (56.84)	1.65(0.8-9-3.07)	0.1
	< 8450	87 (51.18)	41 (43.16)		

DISCUSSION

A high percentage (58.89%) of the study subjects was poorly adherent to the diabetic medications indicating an urgent need to improve adherence. Adherence rates to diabetic medications vary in prior studies. A study by Manobharathi et al in Chidambaram, Tamilnadu reported a poor adherence rate of 60.2%.⁽⁵⁾ In contrast a study in Chennai by Shobhana et al reported a very high prevalence of 75% poor adherence to anti diabetic medications.⁽⁶⁾ Shankar et al also reported a high

prevalence (74%) of non-adherence among rural diabetic population of Kerala.⁽⁷⁾ Systematic review of adherence to medication for diabetes both in developing and developed countries showed that average adherence to oral hypoglycemic medications ranged from 36% to 93%.⁽⁸⁾ one of the reasons for this large variation in medication adherence in these studies could be the different methods for measuring adherence. There are a number of approaches to studying medication-taking behavior. Self-report measures have the benefits of easy to administer, non-intrusive, and able to provide information on attitudes and beliefs about medication. Potential limitations to self-report are that the ability to understand the items, and willingness to disclose information, can affect response accuracy and, thus, questionnaire validity.

The main consequence of poor adherence to medications for glycemic control is decreased glycemic control, leading to the known complications of diabetes, including microvascular and macrovascular diseases and altered lipid metabolism.⁽⁹⁾ In diabetic patients good adherence to treatment, including suggested dietary modifications, physical activity has been shown to be effective in reducing complications and disability, while improving patients’ quality of life and life expectancy.⁽¹⁰⁾ In addition to their positive impact on the health status of patients with chronic illnesses, higher rates of adherence confer economic benefits.

There are many potential reasons for nonadherence to medication and, frequently, more than one is present for any given patient. The reasons for medication poor adherence are multifactorial. In our study education < 10 years of schooling was significantly associated with poor adherence but higher annual direct expenditure associated with diabetic care was not significantly associated with poor adherence. Although socioeconomic status has not consistently been found to be an independent predictor of adherence, some factors reported to have a significant effect on adherence are: poor socioeconomic status, low level of education, unemployment, high cost of medication. The high cost of medicines and care is consistently reported as an important cause of non-adherence in developing countries.⁽²⁾

Several studies found that lower income groups generally spent a larger proportion of their income on diabetes care; urban populations spent more in absolute terms and that cost of complications added heavily to overall costs. Within the diabetes population, low-income individuals bear the highest burden of diabetes.⁽²⁾

An interesting study by Albaz et al concluded that organizational variables (time spent with the doctor, continuity of care by the doctor, communication style of the doctor and interpersonal style of the doctor) are far more important than socio-demographic variables (gender, marital status, age, educational level and health status) in affecting patients’ adherence.⁽¹¹⁾

Duration of disease in our study appears to have a negative relationship with adherence: the longer a patient has had diabetes, the less likely he or she is to be adherent to treatment. Study also shows thrice daily drug regimen was significantly associated with poor adherence. Higher adherence levels were reported by patients required to take less frequent doses (a once-daily dose), compared to those prescribed more frequent doses (three times daily). In general, the more complex the treatment regimen, the less likely the patient will be to follow it. Adherence to oral hypoglycaemic agents has been associated with frequency of dosing. Dailey et al. also reported that patients prescribed a single medication had better short-term and long-term adherence rates than patients prescribed two or more medications. ⁽¹²⁾

There have been a number of studies of compliance with OHAs and the majority indicate that adherence declines as the number of drugs increases. ⁽¹³⁾ Patients may also become frustrated if their preferences in treatment-related decisions are not elicited and taken into account. For example, patients who felt less empowered in relation to treatment decisions had more negative attitudes towards prescribed therapy and reported lower rates of adherence. ⁽¹⁴⁾

Poor glycaemic control (HbA1c > 7%) was present in 52.96% of the patients enrolled in our study. Results from the Diabcare India 2011 study also showed mean HbA1c of $8.97 \pm 2.2\%$ where data of more than six thousand diabetic patients from India was analyzed indicating the poor glycaemic control in India. ⁽¹⁵⁾

CONCLUSION:

A high percentage of the study population was poorly adherent to the diabetic medication. A more concerning fact was the significant association of the non-compliance with poor glycaemic control, which emphasized the role of a repeated patient education regarding drug adherence.

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