

A study to evaluate compliance in patients of diabetes mellitus in a North-Indian tertiary care hospital

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ABSTRACT

Background: The objective of the study was to determine level of adherence and recognize various causative factors which can affect the compliance in the diabetic patients.

Methods: This was an observational study. The study was conducted by enrolling patients of the outpatient department of Medicine of Rajindra Hospital, Government Medical College, Patiala, Punjab. To assess adherence, a questionnaire was administered to the patients - Morisky Medication Adherence Scale (MMAS) -8 item questionnaire. The various factors affecting compliance was determined by a researcher made questionnaire.

Results: Out of a total of 100 subjects, age range extended from 18 years to 80 years. The mean age was 57.52 ± 12.33 years. 51% of patients were females and 49% was males. Analysis of MMAS- 8 item scores of patients showed that 52% of patients had low adherence, 29% had medium while 19% had high adherence to the treatment. Only 30% patients were compliant i.e. with HbA1C value of 7 or less while 70% patients were non-compliant i.e. with HbA1C value of more than 7.

Conclusions: Compliance to medical treatment is influenced by a myriad of factors. In order to promote compliance, it is necessary to increase awareness about the disease, possible complications and treatment guidelines among patients as well as their family members.

Keywords: Diabetes mellitus, Medication adherence, Medication compliance, Morisky Medication Adherence Scale (MMAS) -8 item questionnaire

INTRODUCTION

Diabetes, a major lifestyle disorder, is increasing globally and has become a major public health problem. It refers to a group of common metabolic disorders that share the common phenotype of hyperglycemia. It is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. Insulin deficiency in turn leads to chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism.¹

The prevalence of DM has increased over the years. According to World Health Organization (2016), the

number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014.²

India had 69.2 million people living with diabetes (8.7%) as per the 2015 data. Of these, it remained undiagnosed in more than 36 million people.³ The prevalence of diabetes mellitus has increased to such an extent that India has now earned the notorious nickname of Diabetic Capital of the world.⁴

The management of diabetes mellitus is multi- pronged. The majority of patients with type 2 diabetes fail to control glycemia with diet and exercise and require pharmacotherapy- in general, initially monotherapy with

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. Glycemic control in type 2 diabetes is essential to prevent complications. Hence the holistic approach to the care of the control of diabetes is vital.⁵

Adherence has been defined as “the extent to which a person’s behavior coincides with medical advice.”⁶ Adherence rates are typically higher among patients with acute conditions as compared to those with chronic conditions. Both adherence and compliance terms are often used synonymously. Adherence is directly related to various factors such as education, knowledge, economic status, forgetfulness, lack of will power physician knowledge. Duration of the disease also bears a direct effect on the adherence of the patient of the patient to the treatment. The decline in adherence is most rapid after the first 6 months of therapy. Thus, the overall management of type 2 diabetes should address adherence as well as appropriate medications.⁷

Keeping in mind the predictable future of this disease, this study aims to recognize various causative factors which can affect the compliance in the diabetic patients. This will not only equip us to formulate a sustainable and convenient treatment module but also give us insights to improve the quality of life in these patients in general.

METHODS

It was a cross sectional, questionnaire based survey.

A government teaching and tertiary level care hospital in the state of Punjab (India)-Government Medical College and Rajindra Hospital, Patiala.

One hundred questionnaires were administered to the patients of diabetes mellitus.

Patients having HbA1C >7% at the time of interview. While patients having HbA1C ≤7% at the time of interview was considered as “compliant”.

Inclusion criteria

- Age ≥18 years of age;
- Having type 1 DM/ type 2 DM;
- Providing informed consents; and
- Having diabetes for at least one year.

Exclusion criteria

- Patients with severe cognitive problems.
- Lack of patient’s consent to participate in the study.

Study instrument

The study instrument was a researcher made questionnaire

which was structured to obtain the factors which can affect the compliance among the diabetic patients. It was used to check the compliance of the patient with respect to medication intake, and life style modification in the form of dietary control and exercise. Questionnaire was validated through a pilot study.

Adherence calculation and stratification

Adherence was assessed through the specific eight question patient questionnaire, the Morisky’s instrument that has high reliability and validity, and the patient was considered to be adherent if calculate score >8 (High adherence) moderate adherence (6-8), low adherence (<6). Simple percentage was used to describe different variables.⁸ The permission to use MMAS- 8 item scale was taken from the concerned authorities.

Statistical analysis

The results of observations of individual patients were pooled and analyzed. Statistical analysis was performed using Statistical Program for Social Sciences (SPSS) software version 20.0 Chicago, Illinois, USA. p-value <0.05 was considered statistically significant and p-value <0.01 was considered highly significant.

Trial registration

The study was approved by the institutional ethics committee (GMC/PTA/IEC/108). The trial was registered at the Clinical Trial Registry- India [CTRI.nic.in identifier: CTRI/2016/07/007074] and the World Health Organization [Universal Trial Number: U1111-1169-7289].

RESULTS

Sample characteristics

A total of 100 subjects were included in the study. The mean age was 57.52±12.33 years. The age range extended from 18 years to 80 years (Table 1). Out of 100 patients, 51% of patients were females and 49% was males with an approximate male: female ratio of 1:1 (Table 1).

Majority of the study population were married (87%) compared to 13% unmarried population. Literacy background of patients showed majority were illiterate (27%) followed by post-graduate (21%), primary school (20%), secondary school level of education (19%) and graduation (13%). By occupation, 39% of patients were housewife, followed by retired personals (24%), government employees (19%), businessman (4%) and others (14%).

Around 33% of patients were diagnosed with diabetes for the duration of more than 10 years. While, 31% and 29% of patients were diagnosed between a period of 5-10 years and 1-5 years respectively. 7% patients did not recall the

time of diagnosis. Majority of patients (33%) were taking treatment from 5-10 years while 29% of patients were taking treatment from >10 years and 1-5 years. 9% patients did not recall the time of start of treatment. There was no time gap between diagnosis and treatment in 89% of the patients. Family history of diabetes mellitus was present in 50% of patients while 41% had no such family history. 9% had no knowledge whether family history was present or not. At least, one associated co-morbidity such as hypertension, asthma or osteoarthritis, etc. was present in 57% of the study population.

About 88% of patients had knowledge about the role of dietary restrictions while 76% had awareness of the role of exercise in management of diabetes mellitus. Self monitoring of glucose was done by 4% of people only. Substance abuse (in the form of alcoholism, smoking, opium, etc.) was present with 32% of patients.

Table 1: Demographic characteristics of patients of diabetes mellitus.

	Variables	No. of Patients
Age (Years)	≤20	2 (2%)
	21-40	7 (7%)
	41-60	51 (51%)
	61-80	40 (40%)
	Mean (±SD)	57.52±12.33
	Range	18-80
Gender	Male	49 (49%)
	Female	51 (51%)
Marital Status	Married	87 (87%)
	Unmarried	13 (13%)
Education	Illiterate	27 (27%)
	Primary School	20 (20%)
	Secondary School	19 (19%)
	Graduate	13 (13%)
	Post Graduate	21 (20%)
Occupation	Business	4 (4%)
	Govt.	19 (19%)
	House Wife	39 (39%)
	Retired	24 (24%)
	Others	14 (14%)
HbA1c	≤7	30 (30%)
	>7	70 (70%)
Knowledge Diet Related		88 (88%)
Knowledge Exercise Related		76 (76%)
Self-Monitoring of Glucose		4 (4%)
Substance Abuse		32 (32%)

Compliance on the basis of biochemical parameters

Compliance was measured in terms of a biochemical parameter "HbA1C". Patients with HbA1C value of 7 or less were considered as compliant to the treatment while patients with HbA1C value of more than 7 were considered as non-compliant to the treatment. In this study, only 30% patients were compliant i.e. with HbA1C value

of 7 or less while 70% patients were non-compliant i.e. with HbA1C value of more than 7 (Table 1).

Adherence on the basis of MMAS- 8 item scale

Analysis of MMAS- 8 item scores of patients showed that 52% of patients had low adherence, 29% had medium while 19% had high adherence to the treatment.

Table 2: Summary of patient's responses to the Morisky Medication Adherence Scale (8-Item).

Questions	No	Yes
Do you sometimes forget to take your diabetes medication(s)?	59%	41%
People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your diabetes medication(s)?	80%	20%
Have you ever cut back or stopped taking your medication(s) without telling your doctor, because you felt worse when you took it?	83%	17%
When you travel or leave home, do you sometimes forget to bring along your diabetes medication(s)?	56%	44%
Did you take your diabetes medication(s) yesterday?	2%	98%
When you feel like your diabetes is under control, do you sometimes stop taking your medication(s)?	74%	26%
Taking medication(s) every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your diabetes treatment plan?	79%	21%
How often do you have difficulty remembering to take all your medication(s)?		
• Never/Rarely	33%	
• Once in a while	42%	
• Sometimes	19%	
• Usually	6%	
• All the time	0%	

DISCUSSION

Diabetes mellitus has now become an important public health concern which needs immediate attention of the healthcare professionals. Its optimum control is a major challenge to patients and poses a great burden on the health care system and national economy.

In our study, the mean age of patients with diabetes was 57.52±12.33 years. The age range extended from 18 years to 80 years. Out of 100 patients, 51% of patients were females and 49% was males with an approximate male: female ratio of 1:1. The increased prevalence is directly

related to lifestyle and the stress from various spheres affecting people. Majority of the study population were married (87%) compared to 13% unmarried population. The level of education, employment also plays a significant role. Education status in our study showed majority were illiterate (27%) followed by post-graduate

(21%), primary school (20%), secondary school level of education (19%) and graduation (13%). Highly educated persons are more aware, earn more which is directly related to affordability and results or success of the treatment.

Table 3: A correlation between patients' socio-demographic characteristics and adherence.

		No. of patients	Low adherence	Medium adherence	High adherence
Age (years)	≤20	2 (2%)	1 (50%)	1 (50%)	0 (0%)
	21-40	7 (7%)	4 (57.14%)	2 (28.57%)	1 (14.29%)
	41-60	51 (51%)	27 (52.94%)	14 (27.45%)	10 (19.60%)
	61-80	40 (40%)	20 (50%)	12 (30%)	8 (20%)
Gender	Male	49 (49%)	22 (44.90%)	17 (34.69%)	10 (20.41%)
	Female	51 (50%)	30 (58.82%)	12 (23.52%)	9 (17.65%)
Marital status	Married	87 (87%)	46 (50.57%)	24 (29.88%)	17 (19.54%)
	Unmarried	13 (13%)	6 (46.15%)	5 (38.46%)	2 (15.38%)
Education	Illiterate	27 (27%)	15 (55.55%)	6(22.22%)	6 (22.22%)
	Primary School	20 (20%)	11 (55%)	4 (20%)	5 (25%)
	Secondary School	19 (19%)	9 (47.37%)	6 (31.58%)	4 (21.05%)
	Graduate	13 (13%)	8 (61.54%)	4 (30.77%)	1 (7.69%)
	Post Graduate	21(21%)	9 (42.86%)	9 (42.86%)	3 (14.28%)
Occupation	Business	4 (4%)	2 (50%)	2 (50%)	0 (0%)
	Govt.	19 (19%)	9 (47.37%)	6 (31.58%)	4 (21.05%)
	House Wife	39 (39%)	23 (59.97%)	8 (20.51%)	7 (17.94%)
	Retired	24 (24%)	11 (45.83%)	8 (33.33%)	5 (20.83%)
	Others	14(14%)	7 (50%)	5(35.71%)	3 (21.43%)
Duration since diagnosis	1-5 Yrs	29 (29%)	16 (55.17%)	9 (31.03%)	4 (13.79%)
	5-10 Yrs	31 (31%)	15 (48.39%)	8 (25.81%)	8 (25.81%)
	10 Yrs	33 (33%)	17 (51.52%)	11 (33.33%)	5 (15.15%)
	Can't say	7(7%)	4(57.14%)	1(14.28%)	2(28.57%)
Duration since treatment	1-5 Yrs	29 (29 %)	15 (51.72%)	9 (31.03%)	5 (17.24%)
	5-10 Yrs	33 (33 %)	17 (51.52%)	9 (27.27%)	7 (21.21%)
	10 Yrs	29 (29%)	14 (48.28%)	10 (34.48%)	5 (17.24%)
	Can't say	9(9%)	6(66.67%)	1(11.11%)	2(22.22%)
Family history	Yes	50 (50%)	29 (58%)	13 (26%)	8 (16%)
	No	41 (41%)	16 (39.02%)	16 (39.02%)	9 (21.95%)
	Can't say	9(9%)	7 (77.78%)	0(0%)	2 (22.22%)
Co-morbid condition	Yes	57 (57%)	31 (54.39%)	16 (28.07%)	10 (17.54%)
	No	43 (26%)	21(48.84%)	13 (30.23%)	9 (20.93%)
Knowledge diet related	Yes	88 (88%)	46 (52.27%)	25 (28.41%)	17 (19.32%)
	No	12 (12%)	6 (50%)	4 (33.33%)	2 (16.67%)
Knowledge exercise related	Yes	76 (76%)	37 (48.68%)	24 (31.58%)	15 (19.74%)
	No	24 (24%)	15 (62.50%)	5 (20.83%)	4 (16.67%)
Self-monitoring of glucose	Yes	4 (4%)	0 (0%)	1 (25%)	3 (75%)
	No	96 (96%)	52 (54.16%)	28(29.17%)	16 (16.67%)
Substance abuse	Yes	32 (32%)	16 (50%)	11(34.37%)	5 (15.62%)
	No	68 (68%)	36 (52.94%)	18 (26.47%)	14 (20.59%)

By occupation, 39% of patients were housewife, followed by retired personnels (24%), government employees

(19%), businessman (4%) and others (14%). The high prevalence in housewives and retired personnels may be

due to less physical activity, obesity, increased BMI with age and lower satisfaction with life.

The duration of diabetes plays an important role in management of diabetes. This study showed that most of the patients (33%) had a diabetic history of >10 years. Patients with a long duration of diabetes are at a higher risk of developing complications. Family history of diabetes mellitus was present in 50% of patients while 41% had no such family history. Diabetes is one of the most common inherited diseases. 9% had no knowledge whether family history was present or not.

Majority of patients (33%) were taking treatment from 5-10 years while 29% of patients were taking treatment from >10 years and 1-5 years. 9% patients did not recall the time of start of treatment. At least, one associated co-morbidity (such as hypertension, asthma, osteoarthritis, etc.) was present in 57% of the study population. The overall prevalence of co morbid conditions among the type 2 diabetic patients was 84%.⁹ The 97.5% of patients had at least one comorbid condition in addition to T2DM and 88.5% had at least two.¹⁰

About 88% of patients had knowledge about the role of dietary restrictions while 76% had awareness of the role of exercise in management of diabetes mellitus. The 51.23% diabetic respondents thought exercises should be done to control diabetes while 74.78% respondents thought dietary modifications should be done to control diabetes.¹¹ Studies have documented that self-care among T2DM subjects improved glycaemic control and reduced complications.¹² Self-monitoring of blood glucose was done by 4% of people only. It is widely used as the standard biomarker for the adequacy of glycaemic control that further associates with reduced mortality and reduced incidence of complications in patients with type 2 DM.

Substance abuse (in the form of alcoholism, smoking, opium, etc.) was present with 32% of patients. Substance abuse often compromises the glycemic control of patients further reducing their quality of life. The prevalence of substance abuse was 32.21% among the diabetic individuals.¹³

Analysis of MMAS- 8 item scores of patients showed that 52% of patients had low adherence, 29% had medium while 19% had high adherence to the treatment. It indicates that adherence of patients to the anti-diabetic medications is compromised to a great extent.

The high, medium and low adherence in 0%, 26% and 74% of diabetic patients.¹⁴ The 16.6% of the patients were adherent while 83.3% of the patients were nonadherent.¹⁵ In contrast to our findings, the adherence levels to be 40.95%, 37.14% and 21.90% for high, medium and poor adherence, respectively.¹⁶ Also, in Ethiopian population, 70.4% respondents were adherent while 29.6% were not adherent to their medication.¹⁷ The differences can be attributed to geographical differences as well as

differences in motivational levels amongst various population groups. Another reason can be the difference in the instrument used to ascertain adherence of the patients i.e. whether MMAS- 4 item or MMAS- 8 item scale has been used.

CONCLUSION

Management of a chronic disease always faces the issue of compliance. Identification of the key factors affecting compliance helps in its proper management.

The present study helped in the identification of such factors in diabetic care. Some of these factors were modifiable while others were non-modifiable. The utilization of the healthcare tools to exploit these modifiable can help enhance patient's compliance. This will not only result in improved quality of life of patients but also reduce the burden on healthcare budget.

This study had its own limitations. Small sample size, limited duration of study and geographical isolation limits the generalizability of this study to other population groups. Further studies are, therefore, warranted to validate the results of this study.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee (GMC/PTA/IEC/108)

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