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Research Article

MEDICATION CONCORDANCE AMONG THE OUT-PATIENTS WITH TYPE 2 DIABETES IN KANPUR AT NORTHERN INDIA

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ABSTRACT

Medication nonadherence is a pervasive medical problem that is common among patients with chronic disease generally and type 2 diabetes in particular. There are two types of nonadherence (i) unintentional nonadherence and (ii) intentional nonadherence. To evaluate medication adherence in type 2 diabetes patients, determine the outcome of the therapeutic management in the level of blood glucose. The present study is a prospective cross sectional pilot study, it was conducted for 12 weeks, between January and March 2012, by using research questionnaire, Morisky 8-Item Self-Report. 103 patients are selected randomly and interviewed. Of the selected patients, 20.39% patients were completely lost the follow-up, 5.82% patients were not regularly visiting and 3.88% was declined to give consent. Rest of the 72 patients are the subjected for the further studies. 72 subjects, 62.5% were male and 37.5% were female. 94.44% were married and 75% of the subject was completed their graduation while 15.28% was completed secondary school whereas 9.72% do not have any formal education. The occupation of the subjects represented that 47.22% were employed, 40.28% were self-employed and 12.5% were unemployed. 91.67% of subjects HBA_{1C} level was in abnormal category. The total cholesterol level was also measured, 58.33% subjects were having abnormal level (< 200mg/dl). Medication nonadherence of ambulatory type 2 diabetes patients is seen significant. Missing of dose, forgetfulness and expenditure on medicines were the highly observed factor for the medication compliance. Nevertheless, low level of adherence shown to have considerably affected on patients' blood glucose level since large number subjects had blood glucose level was in abnormal level. Pharmacists can help to upsurge the medication adherence and self-management practices of these subjects in the study site to achieve maximum benefits of prescribed treatment regimen.

Keywords: Intervention, Medication adherence, Diabetes mellitus.

INTRODUCTION

There has been a progressive increase in the incidence of type 2 diabetes worldwide, with a prevalence of about 2%.[1,2] India's embrace of the worst of both Eastern and Western ways is sending lifestyle illnesses such as obesity and diabetes skyrocketing. In 2011, India had 62.4 million people with type 2 diabetes, compared with 50.8 million the previous year, according to the International Diabetes Federation (IDF) and the Madras Diabetes Research Foundation. As the economy started growing, so did the incidence of diabetes. The nationwide prevalence of diabetes in India now tops 9%, and is as high as 20% in the relatively prosperous southern cities. By 2030, the IDF predicts, India will have 100 million people with diabetes.[3] Factors such as uncontrolled diet, sedentary lifestyle, inappropriate therapeutic regimens as well as medication nonadherence have been known to have significant impact on glycemic control and outcome of type 2 diabetes treatment.

However, medication nonadherence is a pervasive medical problem that is common among patients with chronic disease generally and type 2 diabetes in particular.[4,5] A systematic review of adherence to medication for diabetes showed that average adherence to oral antidiabetes medications ranged from 36% to 93%.[6] Medication compliance can be defined as taking the correct medicine in the correct dose at the correct time by a patient as prescribed by the physician. The term compliance is very widely used in the pharmaceutical and medical literatures and the noncompliance indicates that patient ineffectiveness and unable to follow the instructions. Concordance is used to mean the level of relationship between the patient and clinician regarding the nature of the illness and the need for treatment.[7] The term adherence has been used by many as a synonym to compliance, to highlight the patient is allowed to choose whether to adhere to the prescription's and the outcome of the therapy depends on the level of medication adherence and compliance to the treatment regimen to the individual patient. As per the WHO, medication adherence is having five factors: (i) social and economic, (ii) health care team, (iii) therapy, (iv) condition and (v) patient.[8] Beside the poor control over disease, lack of adherence to diabetes treatment would lead to ineffectiveness with successive indications of micro- and macro-vascular complications of diabetes and health care costs become more expensive. Non-adherence is very high beyond disease states, therapeutic regimens and age.[9]

Recent studies have established that lower fasting blood glucose levels are associated with reduced mortality[10] and reduced incidence of complications in patients with type 2 diabetes.[11] However, ensuring that patients take oral hypoglycemic medications as prescribed and achieve normal or near normal blood glucose control is among the most common challenges encountered by physicians and other health care providers involved in the treatment of patients with diabetes.[12] This needs to be addressed during all phases of diabetes treatment[13] which makes it imperative to understand factors affecting patients' adherence to medication in order to identify the areas upon which counseling should be focused as well as assisting in the development of future interventions to improve adherence and outcomes of type 2 diabetes treatment. Adherence to therapy is a challenge not only for patients, but also for health practitioners and researchers. Despite efforts to educate patients and provide interventions to address factors contributing to non-adherence and non persistence to therapy remain high, both across different populations and disease states. A lack of consensus about the use and definitions of adherence, the absence of a gold standard to measure adherence and the use of, primarily, self-report methods also introduce a bias in the results and further complicate adherence research and the assessment of interventions provided.[14] There are two types of non adherence:

1. **Unintentional non adherence** results from practical barriers to adherence, such as:
   i. misunderstanding the prescribing instructions;
   ii. language barriers; and
   iii. frequently and understandably, forgetfulness.

2. **Intentional non adherence** results from the patient's decision not to take the medication as prescribed, i.e., to take less or none or to take it differently than prescribed, such as:
   i. patients may doubt the necessity of taking a daily medication for a condition that they experience
   ii. episodically, while they may have concerns about potential adverse effects of inhaled steroids.[14]

Poor adherence has been shown to decrease the effects of prescribed medications or other treatments and to increase the likelihood of poor outcomes. Though, a few published studies have shown that socio demographic factors, personality and psychosocial variables, patients' attitude and beliefs were among the several factors that can affect adherence to diabetes treatment regimen[15,16], there is a continuing need to routinely assess the likely reasons for nonadherence among patients with type 2 diabetes in clinical practice. This is especially important in developing countries such as India where economic instability and inadequate access to health care facilities might have led to the increased incidence of medication nonadherence. In India, changes in lifestyle as a result of increased urbanization and westernization, as well as genetic factors have also contributed to a substantial rise in type 2 diabetes.[3] The objective of the present study is to evaluate medication adherence in type 2 diabetes patients, determine the

outcome of the therapeutic management in the level of blood glucose.

METHODOLOGY

A registry was created for 250 patients diagnosed with type 2 diabetes who are regularly visiting to a particular community ambulatory care pharmacy, at Kanpur, Uttar Pradesh. The present study is a prospective cross sectional pilot study, it was conducted for 12 weeks, between January and March 2012, by using research questionnaire, Morisky 8-Item Self-Report.[17] The inclusion criteria were adult patients who are diagnosed as type 2 diabetes and who must be under hypoglycemic medication(s) for minimum of three months. The patient visits regularly to one clinic. The study objectives were informed to individual patient. Only those who were interested and who gave consent to participate in the study were only selected. Exclusion criteria were all type 1 diabetes patients and not able to understand the study in vernacular language and who were declined to participate/ not given their consent in the study. The patient visits multiple clinics.

There were 182 patients in this registry with at least one HbA_{1c} and total cholesterol level was measured. From this group, 103 patients are selected randomly and interviewed. Of the selected patients, 21 patients (20.39%) were completely lost the follow-up, 6 patients (5.82%) were not regularly visiting and 4 (3.88%) was declined to give consent. Rest of the 72 patients are the subjected for the further studies. For these 72 patients we administered the research instrument. The instrument for data collection was a structured questionnaire consisting of close ended questions.

The research questionnaire was divided into four parts: (i) the first part contain data related to demography and societal such as age, sex, occupation, educational and marital status, as well as diabetes-specific parameter mainly record of most recent fasting blood glucose (FBG) was measured. The FBG, weight and BMI were routine measured. The blood glucose level was measured using meter (LifeScan OneTouch Ultra2). In the present study, good FBG control means 70mg/dL and poor FBG control means FBG >130mg/dL. This classification was based on the ICMR's guidelines on management of type 2 diabetes.[18] (ii) The second part of the questionnaire contains duration of diagnosis as type 2 diabetes, profile of prescribed antidiabetes medications and non-drug treatment recommendations. (iii) The third section contained 8-item Modified Morisky Adherence Measuring Scale (MMAMS)[19] used in a close ended type of questions. Adherence in this study was defined as all or none response to the 8-item question on the MMAMS. Binary response using categorization of 0 and 1. The patients who adhere to the treatment regimen were designated with 1 and non-adherent was designated with 0. A 5-point response version (never/ rarely/ sometimes/ often/ always). The both kinds were used to assess their sensitivity and predictive validity. Scores for the scale range from 0-4 (dichotomous version) and 0-16 (5-point version) with higher scores indicative of worse adherence (iv) The fourth part contains the evaluation of patients' views on reasons for non-adherence in relation to their own medication adherence. The reasons mentioned for medication non-adherence were as similar as mentioned in some of the literatures.

On an average of 10 to 15 minutes of time was consumed by the each patient to answer all the questions and in some, who are not attended colleges, patients they spent 25 minutes to complete the questionnaire. The questionnaire was translated into the vernacular language for whose cannot understand English language. Only 9 (12.5%) patients who did not understand English language were assisted by the principal investigator and their responses were later translated to English. Out of the 103 copies of questionnaire supplied to patients within the study period, 68 (94.44%) were considered for further studies. The remainder, 4 (5.56%) were not used for analysis because of incomplete questionnaire. Data generated were analyzed using SPSS version 11.0 software and represented as mean and SD. Statistical tools employed as descriptive analysis, chisquare, ANOVA and Student t-test. Confidence Level of significance was set at $P < 0.05$.

RESULTS

Patient characteristics

The average age of the subjects were 49.01 ± 2.5 years. Among 72 subjects, 45 (62.5%) were male and 27 (37.5%) were female. Majority, 68 (94.44%) were married remaining 4 (5.56%) were single. 54 (75%) was completed graduated, 11 (15.28%) was completed secondary school and 7 (9.72%) do not have no formal education. The occupation of the subjects represented that 34 (47.22%)

were employed, 29 (40.28%) were self-employed and 9 (12.5%) were unemployed. Subjects were queried about their knowledge on disease. 45 (62.5%) answered relevantly remaining 27 was answered comparatively less. 60 (83.33%) were received more than 5 medicines including antidiabetic agents and remaining 12 (16.67%) were received less than 5 medicines including antidiabetic agents.

BMI of the subjects was measured, 12 (16.67%) were found to be underweight, 23 (31.94%) were in the normal weight, 18 (25%) were in the overweight and 9 (12.50%) was identified as in underweight.[23] Glycated heamoglobin was categorised into two. Majority of the subjects, 66 (91.67%) HBA_{1C} level was in abnormal category and remaining 6 (8.33%) were in the abnormal range. The total cholesterol level was also measured, maximum subjects 42 (58.33%) subjects were having abnormal level (< 200mg/dl) and remaining 30 (41.67%) subjects total cholesterol were in the normal level.

Comparative Scores of Adherence in various levels of literates Morisky Medication Adherence Questionnaires (MMAQ's) Score in higher level of education

The present study was assessed the patient's adherence between the uneducated, schooling and graduates showed marked significance among them in medication adherence score of 1.96 ± 0.84 and $P < 0.0001$ which is statistically significant. There was statistically significant adherence was observed, 3.03 ± 0.40 and $P < 0.0001$, in the uneducated category of subjects when compared with the remaining two categories of subjects.

The evaluation of the subjects' answers to the 8-item MMAS revealed that 59.95% of the subjects were adherent to their prescribed medication and remaining 40.05% of subjects were non-adherent. The marital status showed statistically significant impact on subjects' in the compliance of medication (Chi-square = 8.733, $P > 0.01$). The subjects who are singles (76.65%) seemed to compile better than the married (23.35%). The average FBS for adherent patients, 141.32 mg/dL was less than those of their non-compliance subjects, 148.65 mg/dL, but the difference shown statistically significant less ($P > 0.01$).

Table No. 1: Patient Characteristics (n = 72)

Parameters	Number (%)	Chi Square	P value
Age (years)			
25 – 35	02 (02.78)		
36 – 45	10 (13.39)		
46 – 55	21 (29.17)		
56 – 65	21 (29.17)		
Above 65	18 (25.00)		
Gender			
Male	45 (62.5)		
Female	27 (37.5)		
Marital Status			
Married	68 (94.44)		
Single	04 (05.56)		
Education Qualification			
Illiterate	54 (75.00)		
Schooling	11 (15.28)		
Graduates	07 (09.72)		
Occupation			
Employed	34 (47.22)		
Self-employed	29 (40.28)		
Unemployed	09 (12.50)		
Disease Knowledge			
Yes	45 (62.50)		
No	27 (37.50)		
Number of Medication			
< 5	60 (83.33)		
> 5	12 (16.67)		
BMI			
Underweight	12 (16.67)		
Normal weight	23 (31.94)		
Overweight	18 (25.00)		
Obesity	09 (12.50)		
HBA_{1C}			
Normal range (> 7%)	66 (91.67)		
Abnormal range (< 7%)	06 (8.33%)		
Total Cholesterol			
Normal range (> 200mg/dl)	42 (58.33) 30 (41.67)		
Abnormal range (<200mg/dl)			

Table 2: Subjects responses to the MMAS (n = 72)

Question	Number (%)	
Response (score coding)	Yes (1)	No (0)
1. Do you sometimes forget to take your pills?	21 (29.17)	51 (70.83)
	07 (09.72)	65 (90.28)
2. 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 medicine?	10 (13.89)	62 (86.11)
	15 (20.83)	57 (79.17)
3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?	04 (05.56)	68 (94.44)
	09 (12.50)	63 (88.50)
	18 (25.00)	54 (75.00)
4. When you travel or leave home, do you sometimes forget to bring along your medication?	23 (31.94)	49 (68.06)
5. Did you take your medicine yesterday?	Total (%)	
6. When you feel like your is under control, do you sometimes stop taking your medicine?	32 (44.44)	
	11 (15.28)	
	09 (12.50)	
7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your blood pressure treatment plan?	07 (09.72)	
	04 (05.56)	
	04 (05.56)	
	02 (02.78)	
	02 (02.78)	
8. How often do you have difficulty remembering to take all your medications?	01 (01.38)	
	Number (%)	Category
	32 (44.44)	Adherent
Distribution of scores	40 (55.56)	Non adherent
0		
1		
2		
3		
4		
5		
6		
7		
8		
Cut-off		
< 1		
= 1		

Assessment of medication adherence in type 2 diabetes patients

All the 72 participants of the study were evaluated by MMAQs at the time of registration and on follow up, medication adherence score was assessed at the beginning of the study first and at the end of the study.

Reported reasons for noncompliance to their prescription's

The study revealed the some of the factors which creates impact on the non-compliance to their oral diabetes agents and the data are presented in the table ???? The following factors are classified into two kinds as: (i) intentional and (ii) non-intentional noncompliance. The most common reason among the subjects were missing of dose, which is a kind of intentional noncompliance was reported by 62 (86.11%). 37 (51.39%) subjects were shown disappointment for having medication on every day and 15 (20.83%) subjects found difficulty in carrying medications while going away from their house. 29 (40.28%) subjects revealed that they neglect of taking medications.

Discussion

Poor medication adherence seems to be a significant barrier to attainment of positive clinical outcomes among type 2 diabetes patients in both developed and developing countries.[22] The study results shows counseling session conducted by clinical pharmacist were able to produce a statistically significant improvement in adherence of the patient towards prescribed medication. Similar study, carried out by Mehuys E et al.[20] found that pharmacist intervention substantially improved both the inhalation technique and medication adherence.

In our study 62% male and 38% female subjects are participated and most of them 58% are age group between 45 year of age and the different results are reported in previous studies conducted in Nigeria.[9] In the our study site 75 % participants are illiterate and only 25 % are educated but in other studies showing 12% illiterate.[9] The damograpic characterictics are also influenced the study because the educate people more follow instructions given by physicians or other healthcare professionals than compared to illiterate patients because may be better understanding about medication and disease.

Botelho et al.[21] and Anderson et al.[22] have shown that socioeconomic factors play a vital role in adherence, as patients who are poor or live on fixed income may be nonadherent because of their inability to afford the cost of prescribed medications. Anderson et al.[22] also showed that patients who have limited access to transportation, live far away from clinics may not likely to adhere to treatment regimens.

The results of present on medication adherence assessment suggest that patients at the baseline possess poor medication adherence and this may be due to various reasons. During the time of baseline assessment we asked the reasons to stop/miss medications to the patients. Following were the reasons pointed out by patients. Most of diabetes patients, were reported that high cost of the medication was one of the reasons for medication non-adherence. As new group of oral hypoglycemic and insulin are very costly and majority of the patients enrolled were from middle class family and from low socio-economic groups. So they couldn't afford the cost of medications. Another reason for non-adherence was

forgetfulness 21 (29.17%). This problem can resolve by using the tools like medication reminder or diary keeping.

Out of 72 diabetes patients, 7 (9.72%) patients miss taking their medication for reasons other than forgetting. Clinical pharmacist can be an effective tool to counsel and educate the patient regarding use of medication. Out of 72 diabetes patients, 10 (13.89%) patients were stopped their medication without telling concerned physician due to lack of knowledge about medicine adverse effects or disease conditions. This may be due to poverty, poor knowledge and attitude of family and society towards the disease. Clinical pharmacist can be an effective tool to counsel the family regarding the disease which will change their attitudes towards it.

Out of 72 diabetes patients 15 (20.83%) are sometimes forgot bring along medication while travel to other place. This problem can be solved by clinical pharmacist by educate the patients about importance of medicine on regular use in blood sugar control.

In our study only 12.5% saying they stop to take medication when they fell like under control and 18 (25%) taking medication everyday is a real inconvenience for some patients. This can also solved by clinical pharmacist by the patient counselling. Out of 72 diabetes patients 23 (31.94%) have difficulty remembering to take all medications. For this patient can make diary and other reminders for to take medicine timely. The study concludes that pharmacist provided patient counseling found to have significant influence on improvement in the patient's adherence to prescribed therapy. The pharmacist provided patient counseling helps to improve inhaler techniques and understanding of their treatment regimen. Further the study suggests that, the pharmacist intervention is essential in the management of chronic diseases. Pharmacist provided patient counseling helps in improving medication adherence and which will improve the therapeutic outcome of the patient.

Conclusion

Medication nonadherence of ambulatory type 2 diabetes patients is seen significant. The present study revealed that the missing of dose, forgetfulness and expenditure on medicines were the highly observed factor for the medication compliance. Nevertheless, low level of adherence shown to have considerably affected on patients' blood glucose level since large number subjects had blood glucose level was in abnormal level. Pharmacists can help to upsurge the medication adherence and self-management practices of these subjects in the study site to achieve maximum benefits of prescribed treatment regimen. Future studies were planned to increase sample sizes, larger representation of various kind of population of patients and applying more objective measures, and less reliance on self-report to measure adherence.

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