Compliance to Anti-Diabetic Drugs: Observations from the Diabetic Clinic of a Medical College in Kolkata, India

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ABSTRACT

Background: The poor glycaemic control among the patients with type 2 diabetes constitutes a major public health problem and a major risk factor for the development of diabetes complications.

Aim of the Study: To study the compliance rate of the patients with type 2 diabetes to the prescribed medications, to find out its correlation with different socio-demographic factors and other patient characteristics and to find out the reasons behind the non-compliance, if any.

Settings and Design: This cross sectional study was conducted on the patients with type 2 diabetes, who Attended the Diabetic Clinic of a Medical College in Kolkata, India.

Methods and Material: The patients of type 2 diabetes who attended the diabetes clinic between April to August 2012 were recruited in the study by systematic random sampling and they were interviewed by using the help of a structured interview schedule. The patients who reported taking less than 80% of their prescribed anti-diabetes medicines in the preceding week and had HbA1C of > 7% were considered to be non-compliant.

Statistical Analysis Used: The data was analyzed by using the SPSS software. The Chi-square test was used to assess the association of the compliance with the different study variables. A binary logistic regression analysis helped in identifying the factors which contributed to the non-compliance.

Results: The compliance rate to the anti-diabetic drugs was found to be 57.7%. A univariate analysis showed that it decreased significantly with increasing age and that it was also significantly lower among males, illiterates, those with a poor per capita monthly income and those who had a longer duration of diabetes. It varied significantly with the type of drugs, being lowest with an oral drug and insulin combination (43.4%). No knowledge on the complications of diabetes was significantly associated with a lower compliance. The binary logistic regression also helped in identifying these as the significant contributory factors. The common reasons behind the non-compliance were forgetfulness (44.7%) and financial constraints (32.7%).

Conclusion: It can be concluded that the compliance to anti-diabetic drugs was quite poor among the participants. Increasing age, the male sex, illiteracy, a low monthly income and a longer duration of diabetes were significantly associated with the non compliance. A more concerning fact was the significant association of the non-compliance with the types of drug regimens and a lack of knowledge on the complications of diabetes, which emphasized the role of a repeated patient education regarding the basic aspects of diabetes.

INTRODUCTION

The global increase in the prevalence of diabetes is due to the huge population growth, aging, urbanization, an increase in obesity and a lack of physical activity. The major determinants of this epidemic are the rapid epidemiological transitions which are associated with the changes in the dietary patterns and the decreased physical activity.

Unlike the west, where the older populations are most affected, the burden of diabetes in the Asian countries is disproportionately high in the young to middle-aged adults [1, 2].

Although there is an increase in the prevalence of type 1 diabetes, the major driver of this epidemic is type 2 diabetes, which accounts for more than 90% of all the diabetes cases [3] India currently leads the world, as it has the largest number of diabetics and is considered as the "diabetes capital of the world" [3]. The International Diabetes Federation (IDF) has estimated the total number of diabetic subjects to be around 40.9 million in India, which will further rise to 69.9 million by the year 2025 [4].

A poor and inadequate glycaemic control among the patients with type 2 diabetes constitutes a major public health problem and a major risk factor for the development of diabetes complications [5]. Self care in the form of adherence to diet and drugs, blood glucose monitoring, foot care, exercise and recognition of the symptoms, are the crucial elements which are required for a secondary prevention [6]. However, among the people with diabetes who had received the diabetes health education from a treatment facility, only 30% were compliant with the drug regimens, 37% with diet and 19% with exercise. The non-compliance was higher among the lower socioeconomic groups [7]. A poor access to drugs, the high costs of drugs, an unequal distribution of the health providers between the urban and the rural areas and cultural barriers further hamper the self-care activities in developing countries such as India [8-10].

In the light of the above findings, the present study was conducted in the diabetic clinic of a medical college in Kolkata, India with the aim of studying the compliance rate of the patients with type 2 diabetes to the prescribed medications, to find out its correlation with different socio-demographic factors and other patient characteristics and to find out the reasons behind the non-compliance, if any.

MATERIALS AND METHODS

This cross-sectional study was done in the diabetic clinic of Calcutta National Medical College and Hospital, Kolkata, India during the period from April 2012 to August 2012. The study protocol was approved by the ethics committee of this institution and informed consents were obtained from all the study participants who were patients who suffered from type 2 diabetes and had attended the diabetic clinic of this institution during the study period.

The sample size was determined by using the formula, 4PQ/L2, where

P = prevalence of the compliance to anti-diabetic drugs

Q = 1 − P

L = allowable error

Considering the prevalence of the compliance to anti-diabetic drugs to be 30% [7], with the allowable error being 10% of the prevalence, the initial sample size came out to be 933. However, keeping the time constraints and the feasibility of the study in mind, 50% of the initial sample size was taken into account, which came out to be 466.5, which was then rounded off to 470.

The study participants were selected on the basis of the following

Inclusion Criteria:
1) Patients with type 2 diabetes of at least 3 months duration following the initial diagnosis.
2) The patients who were aged 20 years or above.
3) The patients who were non-pregnant or non-puerperal at the time of the interview (for female patients).
4) The patients who had a recent laboratory report on the glycosylated haemoglobin (Hb A1C) levels.
5) Those who were not seriously ill.
6) Those who gave informed consents to participate in the study.
7) Those who were not previously interviewed by the researchers on a previous occasion during the study period.

The diabetic clinic in this institution runs only on the Friday of a week with a foot-fall of 55 patients of type 2 diabetes, on an average. In order to carry out the study in a proper manner, not more than 30 patients were interviewed in each week. On each day, the participants were selected by systematic random sampling, considering the sampling interval on an average to be 2 (55/30). The patients who met the inclusion criteria and gave informed consents to participate, were included in the study. In this manner, the full sample size of 470 was reached in five months time. Each participant was interviewed by using a pre-designed, pre-tested, structured interview schedule which included socio-demographic variables like age, sex, the educational and the marital status, the per-capita monthly income, and specific questions on the duration on diabetes, the type of medications which were prescribed, the compliance to anti-diabetic drugs, the diet plan and the exercise schedule, and the knowledge on the complications of diabetes.

The HbA1C report was also recorded at the same time. The recent prescriptions were studied in detail for cross-checking the data which was collected from the individual patients' interviews.

A patient who was prescribed the necessary anti-diabetic medications and was given advice on the proper diet and exercise schedule for his or her diabetes, but who did not follow these, and had an HbA1C level of more than 7% as per the American Diabetic Association Criteria (ADA position statement 2012) [11], at the time of the interview, was considered as non-compliant. The patients who reported taking less than 80% of their prescribed anti-diabetes medicines in the preceding week were considered as non-compliant [12].

A non-compliance to exercise was considered when a patient reported of exercising or brisk walking (for at least 20 minutes) for less than five days in the preceding week. Similarly, a non-compliance to diet was considered when a patient reported of following the diet plan for less than five days in the preceding week.

The knowledge regarding the complications of diabetes was considered adequate when a patient could mention heart and kidney diseases, leg ulcers and ocular problems. On mentioning one or more of these, but not all, the patient was considered to have some knowledge.

STATISTICAL ANALYSIS

The data was analyzed by the Statistical Package for Social Sciences (SPSS, version 19). The Chi-square test was applied to assess the association of the compliance/non-compliance with the different socio-demographic and patient characteristics. All the variable-associations which showed a p value < 0.2, were further subjected to a binary logistic regression analysis to determine the factors which were associated with the non-compliance. A p value of < 0.05 was considered to be statistically significant.

RESULTS

The mean age of the participants was 42.64 (SD 15.70) years. Among them, 66.4% (312/470) were males while 33.6% (158/470) were females and 20.6% (97/470) were illiterate while 79.4% (373/470) were literate. 76.8% (361/470) were married, while 23.2% (109/470) were single and 36.6% (172/470) had a monthly per capita family income of less than Rs. 1000.00, while 63.4% (298/470) had a monthly per capita income of Rs. 1000.00 and above.

Regarding the other patient characteristics, it was found that 46.1% (217/470) were diabetic for less than five years and that 53.8% (253/470) had diabetes for five years and more. At the time of the present study, 48.9% (225/470) were put on oral hypoglycaemic agents (OHA) alone, 15.3% were put on insulin alone and 36.8% (173/470) were prescribed both OHA and insulin.

The compliance rate to the anti-diabetic drugs was found to be 57.7% (271/470), while 42.3% (199/470) were non-compliant. It was also observed that only 36.4% (171/470) and 27.0% (127/470) of the study participants had followed the prescribed diet plan and the exercise schedule respectively in the preceding week. Fifty-nine percent (279/470) of the participants had either adequate or some knowledge about the complications of diabetes, while nearly 41% (191/470) had no knowledge about these.

A univariate analysis showed that the compliance to the anti-diabetic drugs decreased significantly (p = 0.039) with an increase in

age and that it was lowest (48.3%) in the age group of 60 years and above. The compliance rate was also significantly lower among males (p = 0.006), among those who were illiterate (p = 0.022) and among those had a monthly per capita income of less than Rs 1000.00 (p = 0.03). But it had no significant association with the marital status (p > 0.05) [Table/Fig-1].

The compliance to the drugs was significantly lower among those who had diabetes for five years or more (p = 0.005) and it varied significantly with the prescribed drug regimen (p = 0.00), being highest among those who were put on OHA only (69.3%) and lowest among those who were prescribed both OHA and insulin (43.4%). However, it was not significantly associated with the following of the prescribed diet plan or the exercise schedule (p > 0.05). Having either adequate or at least some knowledge about the complications of diabetes was significantly associated with a higher compliance rate (p = 0.002) [Table/Fig-1].

Socio-Demographic and Patient Characteristics	Compliant with drug therapy	Non-compliant with drug therapy	Chi-square and p value
Age (years)			
< 50 (n = 143)	91 (63.6)	52 (36.4)	x^2 (1) = 6.51
50 – 59 (n = 207)	122 (58.9)	85 (41.1)	p = 0.039
≥ 60 (n = 120)	58 (48.3)	62 (51.7)	
Sex			
Male (n = 312)	166 (53.2)	146 (46.8)	x^2 (1) = 7.54
Female (n = 158)	105 (66.5)	53 (33.5)	p = 0.006
Education			
Illiterate (n = 97)	46 (47.4)	51 (52.6)	x^2 (1) = 5.25
Literate (n = 373)	225 (60.3)	148 (39.7)	p = 0.022
Marital Status			
Married (n = 361)	201 (55.7)	160 (44.3)	x^2 (1) = 2.50
Single (n = 109)	70 (64.2)	39 (35.8)	p = 0.114
Monthly Per Capita Income (Rs)			
<1000 (n =172)	88 (51.2)	84 (48.8)	x^2 (1) = 4.69
≥ 1000 (n =298)	183 (61.4)	115 (38.6)	p = 0.03
Duration of Diabetes			
< 5 years (n = 217)	140 (64.5)	77 (35.5)	x^2 (1) = 7.76
≥ 5 years (n = 253)	131 (51.8)	122 (48.2)	p = 0.005
Type of Medication			
OHA alone (n = 225)	156 (69.3)	69 (30.7)	x^2 (1) = 27.20
Insulin alone (n = 72)	40 (55.6)	32 (44.4)	p = 0.000
OHA and insulin (n = 173)	75 (43.4)	98 (56.6)	
Followed Diet Plan			
Yes (n = 171)	108 (63.2)	63 (36.8)	x^2 (1) = 3.33
No (n = 299)	163 (54.5)	136 (45.5)	p = 0.068
Followed Exercise Schedule			
Yes (n = 127)	79 (62.2)	48 (37.8)	x^2 (1) = 1.47
No (n = 343)	192 (56.0)	151 (44.0)	p = 0.225
Knowledge on complications of diabetes			
Adequate or some knowledge (n = 279)	177 (63.4)	102 (36.6)	x^2 (1) = 9.40
No knowledge (n = 191)	94 (49.2)	97 (50.8)	p = 0.002

[Table/Fig-1]: Association of compliance to anti-diabetic drugs with different demographic and patient characteristics

Factors	Odds Ratio (95% Confidence Interval)	P value
Age (years)		
< 50	1	
50 – 59	1.31 (1.11 – 4.37)	0.043
≥ 60	2.96 (1.49 – 5.85)	0.012
Sex		
Male	1	
Female	0.67 (0.11 – 0.82)	0.021
Education		
Illiterate	1	
Literate	0.83 (0.46 – 0.95)	0.039
Marital Status		
Married	1	
Single	0.55 (0.12 – 1.12)	0.584
Monthly per Capita Income (Rs)		
<1000	1	
≥ 1000	0.77 (0.13 – 3.89)	0.041
Duration of Diabetes		
< 5 years	1	
≥ 5 years	5.61 (1.98 – 13.33)	0.003
Type of Medication		
OHA alone	1	
Insulin alone	3.12 (1.10 – 7.81)	0.019
OHA and insulin	9.31 (4.54 – 21.72)	0.000
Followed Diet Plan		
Yes	1	
No	1.81 (0.72 – 3.04)	0.211
Knowledge on complications of diabetes		
Adequate or some knowledge	1	
No knowledge	7.24 (2.15 – 19.41)	0.001

[Table/Fig-2]: Logistic regression analysis of factors associated with non-compliance to anti-diabetic drug therapy

A binary logistic regression analysis showed that the risk of the non-compliance to the anti-diabetic drug therapy increased as the age increased and that the risk was highest in the age group of 60 years and above (OR = 2.96, p = 0.012). But there was a significantly lower risk of the non-compliance (protective effect) among females (OR = 0.67, p = 0.021), literates (OR = 0.83, p = 0.039) and among those with a monthly per capita income of Rs. 1000.00 or more (OR = 0.77, p = 0.041). There was a significantly higher risk of the non-compliance among those who had diabetes for five years or more (OR = 5.61, p = 0.003). Thecombination of insulin and OHA had the highest odds of non- compliance to the anti-diabetic drugs (OR = 9.31, p = 0.000). A significantly higher risk of non-compliance was found to be associated with no knowledge about the complications of diabetes (OR = 7.24, p = 0.001) [Table/Fig-2].

The most common reason behind the non-compliance to the drugs was found to be forgetfulness (44.7%), which is followed by financial constraints (32.7%), being busy with work (23.1%) and too many medicines being prescribed (15.6%). A smaller proportion (11.6%) of patients also mentioned a feeling of well-being and cure as one of the reasons behind their non-compliance [Table/Fig-3].

Reasons	Number (%)
Forgetfulness	89 (44.7)
Financial constraints	65 (32.7)
Busy with work	46 (23.1)
Too many medicines	31 (15.6)
Feeling of well-being and cure	23 (11.6)
Frequent side effects	14 (7.0)
Trying alternative medicines	11 (5.5)

[Table/Fig-3]: Reasons for non-compliance to anti-diabetic drugs (n = 199)*

DISCUSSION

The compliance to the chronic disease management such as diabetes mellitus, is reportedly variable [13]. Expectedly, the patient non-compliance to the prescribed hypoglycaemic medications could decrease the treatment effectiveness [14,15]. An attempt was made in the present study, to find out the association of various socio-demographic factors and other patient characteristics with the compliance to medications and the reasons behind the non-adherence, as were reported by the patients.

In the present study, the compliance rate to the anti-diabetic drugs was found to be 57.7%. This, though was quite undesirable, was higher than that (30%) which was reported by Shobhana R et al., (1999) [7]. A systematic review on the compliance to medication among diabetic patients, showed that the average compliance to the oral hypoglycaemic agents ranged from 36%-93% [13]. In a study from Saudi Arabia, the overall prevalence of the therapeutic compliance of the participants was found to be 32.1% [12].

In addition to the rate of compliance to the medications, it was also observed in the present study, that only 36.4% and 27.0% of the study participants had followed the prescribed diet plan and the exercise schedule respectively in the preceding week. More or less similar observations were made by Shobhana R et al., 37% compliance with diet and 19% compliance with exercise [7]. Jabbar et al., (2007) from Pakistan also reported a very poor compliance, with the diet and exercise schedules being 33% and 19% respectively [16].

Both the univariate and the binary logistic regression analyses in the present study showed that the compliance to the drug therapy had decreased significantly with an increase in age. The compliance rate was also significantly lower among males and among those who were illiterate. But it had no significant association with the marital status. Khan AR et al., (2012) [12] from Saudi Arabia and Kalyango JN et al., (2008) from Uganda [17] found no significant association between the age or marital status and the non-compliance to the anti-diabetic drugs. However, both of these studies [12,17] reported the male sex and a poor educational status to be significantly associated with the non-compliance.

The present study showed that the compliance rate was also significantly lower among those who had a poor monthly per capita income. Shobhana R et al., from India reported that the non-compliance was higher among the lower socioeconomic groups [7]. Another study reported that those with a family income of less than five Monthly Minimum Wages (MMW) had shown a lower compliance as compared to those with higher incomes [18].

The binary logistic regression analysis which was done in the present study, revealed a significantly higher risk of the non-com-

pliance to medications among those had diabetes for five years or more. Khattab M et al., (2009) from Jordan also reported a significant association of an increased duration of diabetes with increased odds of having poorly controlled diabetes, which indicated non-compliance [5]. A similar observation was also made by Gimenes HT et al., (2009) [19].

The present study showed that as compared to OHA alone, the insulin alone regimen had significantly higher odds of non-compliance, while a combination of insulin and OHA had the highest odds of Non-Compliance to the Anti-Diabetic drugs. A multivariate analysis which was done by Khattab M et al., also revealed that as compared to the patients who were on oral Anti-Diabetic agents alone, those who were on other treatment modalities were more likely to be poorly controlled. Insulin, in combination with oral anti-diabetic agents, was associated with increased odds of a poor glycaemic control [5].

In the present study, a significantly higher risk of the non-compliance to drugs was found to be associated with the patients who had no knowledge on the complications of diabetes. Wabe NT et al., (2011) also reported that the compliance to drugs was significantly higher among the patients who were aware about the complications of diabetes (p < 0.001) [20].

In the present study, the most common reason behind the Non-Compliance to drugs was found to be forgetfulness, followed by financial constraints, being busy with work, too many medicines being prescribed and a feeling of being well and cured. Pascal et al., (2012) from eastern Nigeria reported that the most common reason behind the Non-Adherence to medications by the diabetic patients was financial constraints. The other common reasons included forgetfulness and a feeling of being well [21].

LIMITATIONS OF THE STUDY

The present study was not without limitations. Firstly, the cross-sectional nature of the study did not allow a follow-up, which would have provided a better design for delving into the problem of non-compliance. Secondly, there was always a chance of over-reporting of the compliance, which was involved with the self reporting of the patients, which was however, to some extent, corrected by corroborating with the HbA1C level. Thirdly, the quantitative nature of the data could not properly highlight the reasons for the non-compliance from the patients' perspective, which would have been better revealed by conducting in-depth interviews or focus group discussions. Nevertheless, this study has left scope for a future research in these areas.

CONCLUSIONS

It can be concluded from the present study, that the compliance to the anti-diabetic drugs was quite poor among the participants. The factors like increasing age, the male sex, illiteracy, a low monthly income and the duration of diabetes were significantly associated with the non compliance. A more concerning fact was the association of the non-compliance with the types of drug regimens and a lack of knowledge on the complications of diabetes, which indicated a need for a repeated patient counseling and education regarding the basic aspects of type 2 diabetes. Financial constraints was one of the common reasons behind the non-compliance, which warranted actions like a supply of free medicines from the hospital and the establishment of fair price shops in the government-run hospitals to make the drugs affordable to all.

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