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Original Research Article

Prospective Observational Assessment of the Compliance to Anti-Diabetic Drugs at a Tertiary Centre in Bihar, India

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Abstract

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

Aims and objectives: To study the compliance rate of patients with type 2 diabetes to the prescribed medications; to find out its correlation with different socio-demographic factors and other characteristics of the patient; and to determine the causes of the non-compliance, if any.

Methods and Materials: A cross-sectional study was conducted on a random sample of 270--type 2 diabetic patients (M:F 178:92). The patients who reported taking less than 80% of their prescribed anti-diabetes medicines in the preceding week and had an HbA1C of > 7% were considered to be non-compliant.

Results: The compliance rate for the anti-diabetic drugs was found to be 57.78%, while 42.22% were non-compliant. A univariate analysis showed that the compliance with the anti-diabetic drugs decreased significantly with an increase in age and that it was lowest in the age group of 60 years and above. The compliance rate was also significantly lower among males, those who were illiterate, and young males, those who were illiterate, and those who had a monthly per capita income of less than Rs. 1200. The compliance with the prescribed drugs varied significantly depending on the prescribed drug regimen ($p = 0.001$), being highest among those who were put on OHA alone at 68.94% and lowest among those who were prescribed both OHA and insulin, at 43.43%. Also, compliance with the prescribed drugs was significantly lower among those who had diabetes for five years or more ($p = 0.004$). It was not, however, significantly associated with following the prescribed diet or exercise schedule ($p > 0.05$). The common reasons behind the non-compliance were forgetfulness (35.96%) and financial constraints (28.07%).

Conclusion: It can be concluded that the compliance with 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 non-compliance. A more concerning finding was the significant link between noncompliance with the types of drug regimens and a lack of knowledge about diabetes complications, underscoring the importance of repeated patient education about the fundamentals of diabetes.

Keywords: Type-2 diabetes, Anti diabetics drugs, Compliance, Odds Ratio, Confidence Interval

Introduction

Due to the rapid population expansion, ageing, urbanisation, rise in obesity, and lack of physical activity, diabetes prevalence is increasing globally. The major determinants of this epidemic are the rapid epidemiological transitions, which are associated with changes in dietary patterns and decreased physical activity. Unlike in the west, where the older populations are most affected, the burden of diabetes in Asian countries is disproportionately high in 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 diabetes cases [3]. India currently leads the world as it has the largest number of diabetics and is considered the "diabetes capital of the world"[3]. According to the International Diabetes Federation (IDF), India currently has 40.9 million diabetics and that figure is expected to increase to 69.9 million by the year 2025[4]. Poor and inadequate glycaemic control among 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 that are required for secondary prevention [6]. However, among the people with diabetes who had received diabetes health education from a treatment facility, only 30% were compliant with the drug regimens, 37% with diet, and 19% with exercise. The lower socioeconomic groups showed a higher rate of non-compliance [7]. Poor drug access, high drug costs, unequal distribution of health providers between urban and rural areas, and cultural barriers all impede self-care activities in developing countries such as India [8-10].

Aims and objectives: To study the compliance rate of patients with type 2 diabetes who take their prescribed medications as directed, to determine how this rate correlates with various socio-demographic indicators and other patient characteristics, and to identify any reasons for non-compliance.

Materials and Method

This cross-sectional study was conducted on a random sample of 270 type 2 diabetic patients (M:F 178:92) at the pharmacology department in collaboration with the medicine department, Jannayak Karpoori Thakur Medical College & Hospital, Madhepura, Bihar (India). The study was done on 270 patients diagnosed with T2DM. All patients that were enrolled gave their consent. The study was carried out over a period of 6 months, from December 2021 to May 2022. After receiving approval from the institutional ethical committee, the present study has been carried out in the Department of pharmacology at Jannayak Karpoori Thakur Medical College & Hospital, Madhepura, Bihar (India).

The following criteria were used to select s tudy participants:

Inclusion Criteria

a. Those who give informed consent to p articipate in the study.
b. The patients who were aged 30 years or
c. Patients with type 2 diabetes of at least 6 months duration following the initial
d. Patients who have recently had their glycosylated haemoglobin (Hb A1C) levels tested
e. Those who were not serious
f. Those who had not previously been interviewed by the researchers on a previous occasion during the study.
g. The patients who weren't puerperial or pregnant when the interview took place (for female patients)

In order to carry out the study in a proper manner, no more than 20 patients were interviewed each week. The participants were chosen by systematic random sampling on each day. The patients who met the inclusion criteria and gave informed consent to participate in the study were included in the study. In this manner, the full sample size of 270 was reached in six months' time. Each participant was interviewed by using a pre-designed, pre-tested, structured interview schedule which included socio-demographic variables like age, sex, education, and marital status; the per-capita monthly income; and specific questions on the duration of diabetes, the type of medications which were prescribed, the compliance with anti-diabetic drugs, the diet plan and the exercise schedule, and the knowledge of the complications of diabetes. At the same time, the HbA1C report was also written down. The data gathered from the patient interviews was crosschecked by thoroughly analysing recent prescriptions. A patient who was advised on the proper food and exercise schedule for their diabetes and was provided the necessary anti-diabetic drugs, but who disobeyed these instructions and had a HbA1C level of more than 7% according to the American Diabetes Association Criteria (ADA position statement 2012) [11], at the time of the interview, was considered non-compliant. The patients who reported taking less than 80% of their prescribed anti-diabetic medicines in the preceding week were considered non-compliant [12]. A patient's non-compliance with exercise was considered when a patient reported exercising or brisk walking (for at least 30 minutes) for fewer than five days in the preceding week. Similarly, a non-compliance diet was considered when a patient reported following the diet plan for less than five days in the preceding week. When a patient could mention heart and kidney disorders, leg ulcers, and eye issues, it was considered that they had adequate knowledge of the complications of diabetes. The patient was considered to have some knowledge if they mentioned one or more of these, but not all of them.

Statistical Analysis

The data was analysed by the Statistical Package for Social Sciences (SPSS, version 22) and Microsoft Excel 16. The Chi-square test was applied to ascertain the association between compliance or non-compliance with the different socio-demographic and patient characteristics. A p value of ≤ 0.05 was considered to be statistically significant.

Results

The participants' mean age was 40.5± 14.70 years (Mean± SD). Among them, 65.93% (178/270) were males, while 34.07% (92/270) were females, and 20.04% (55/270) were illiterate, while 79.96% (215/270) were literate. 77.03% (208/270) were married, while 22.96% (62/270) were single, and 37.04% (100/270) had a monthly per capita family income of less than Rs. 1200.00, while 62.96%(170/270) had a monthly per capita income of Rs. 1200.00 and above. Regarding the other patient characteristics, it was found that 46.29% (125/270) had been diabetic for less than five years and that 53.70% (145/270) had had diabetes for five years or more. At the time of the present study, 48.89% (132/270) were put on oral hypoglycemic agents (OHA) alone, 14.45% (39/270) were put on insulin alone, and 36.67% (99/270) were prescribed both OHA and insulin. It was also observed that only 36.29% (98/270) and 27.03% (73/270) of the study participants had followed the prescribed diet plan and the exercise schedule respectively in the preceding week, while 63.70% (172/270) of the participants had not followed the prescribed diet plan. 58.89% (159/270) of the participants had either adequate or some knowledge about the complications of diabetes, while nearly 41.11% (111/270) had no knowledge

about these. The compliance rate for the anti-diabetic drugs was found to be 57.78% (156/270), while 42.22% (114/270) were non-compliant. A univariate analysis showed that the compliance with the anti-diabetic drugs decreased significantly (p = 0.039) with an increase in age and that it was lowest (48.15%) in the age group of 60 years and above. The compliance rate was also significantly lower among males (p = 0.005), those who were illiterate (p = 0.023), and young males (p = 0.005), those who were illiterate (p = 0.023), and those who had a monthly per capita income of less than Rs 1200.00 (p = 0.03). But it had no significant association with marital status (p> 0.05). The compliance with the prescribed drugs varied significantly depending on the prescribed drug regimen (p = 0.001), being highest among those who were put on OHA only 91 (68.94%) and lowest among those who were prescribed both OHA and insulin 43 (43.43%). The compliance with the prescribed drugs was significantly lower among those who had diabetes for five years or more (p = 0.004). It was not, however, significantly associated with following the prescribed diet or exercise schedule (p > 0.05). A higher compliance rate was significantly associated with having adequate or at least some knowledge of the complications of diabetes(P=0.003)[Table-1].

Table 1: The relationship between compliance, non-compliance, and logistic regression analysis of factors related to anti-diabetic drugs and various demographic and patient characteristics.

Socio-Demographic and Patient characteristics	Number of compliant with drug therapy (%)	Number of Non-compliant with drug therapy (%)	Odds Ratio (95% Confidence Interval)	Chi- square and p value
Age (years)				
< 50 (n = 94)	59 (62.76)	35 (37.23)	01	p = 0.032
50–59(n = 122)	71 (58.19)	51 (41.80)	1.31 (1.09 – 4.31)	
≥60 (n = 54)	26 (48.15)	28 (51.85)	2.92 (1.38 – 5.60)	
Sex				
Male(n = 178)	95(53.37)	83(46.63)	01	x^2 (1) = 7.52 p = 0.005
Female(n= 92)	61 (66.30)	31(33.69)	0.68 (0.12 – 0.80)	
Education				
Illiterate(n= 55)	26(47.27)	29(52.72)	01	x^2 (1) = 5.21 p = 0.023
Literate(n=215	130(60.4)	85(39.53%)	0.54 (0.10 – 1.11)	
Monthly Per Capita Income (Rs)				
<1200 (n =100)	51 (51)	49 (49)	01	x^2(1) = 4.51 p = 0.03
≥1200(n =170)	104 (61.17)	66 (38.82)	0.72 (0.10 – 3.78)	
Duration of Diabetes				
< 5 years (n = 125)	81(64.80)	44(35.20)	01	x^2(1) = 6.73 p = 0.004
≥5 years (n = 145)	75(51.72)	70(48.28)	5.60(1.98 – 13.33)	
Type of Medication				
OHA alone (n=132)	91 (68.94)	41 (31.06)	01	x^2(1)= 26.10 p = 0.001
Insulin alone (n = 39)	22(56.41)	17 (43.59)	3.14 (1.12 – 7.62)	

OHA and insulin(n = 99)	43(43.43)	56 (56.56)	9.25 (4.50 – 21.40)	
Followed Diet Plan				
Yes (n = 98)	62 (63.27)	36 (36.73)	01	x^2 (1) = 3.32 p = 0.05
No (n = 172)	94 (54.65)	7 8 (45.35)	1.80 (0.75 – 3.02)	
Knowledge on complications of diabetes				
Adequate or some knowledge (n= 159)	101 (63.52)	58 (36.48)	01	x^2 (1) = 9.20 p= 0.003
No knowledge (n = 111)	55 (49.55)	56 (50.45)	7.20 (2.10 – 17.21	

A binary logistic regression analysis showed that the risk of non-compliance with the anti-diabetic drug therapy increased as age increased and that the risk was highest in the age group of 60 years and above (OR = 2.92, p = 0.032). But there was a significantly lower risk of non-compliance (protective effect) among females (OR = 0.68, p = 0.005), literates (OR = 0.54, p = 0.023) and those with a monthly per capita income of Rs. 1200.00 or more (OR = 0.72, p = 0.03). There was a significantly higher risk of non-compliance among those who had diabetes for five years or more (OR =5.60, p = 0.004). The combination of insulin and OHA had the highest odds of non-compliance of the anti-diabetic drugs (OR = 9.25, p = 0.001). A significantly higher risk of non-compliance was found to be associated with no knowledge about the complications of diabetes (OR = 7.20, p = 0.003) [Table-1].

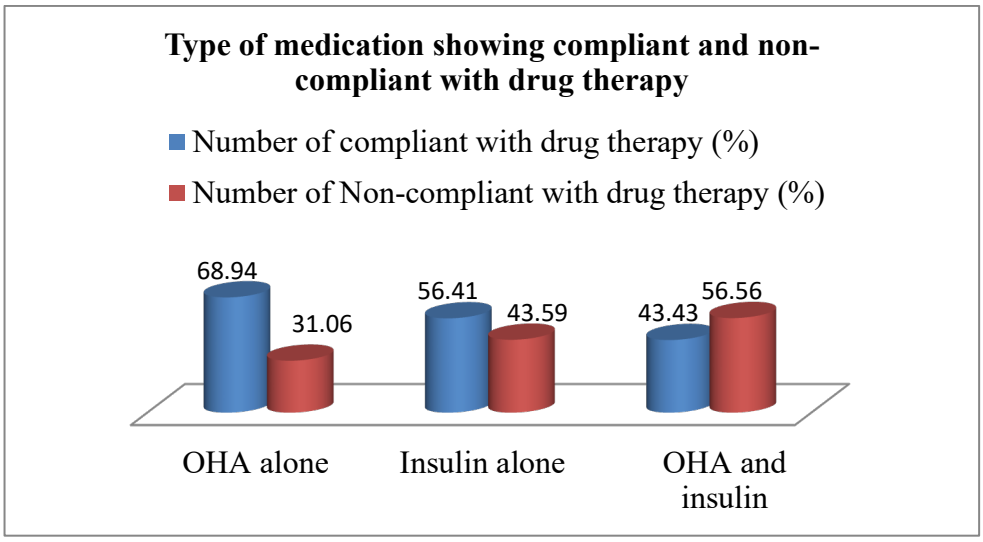
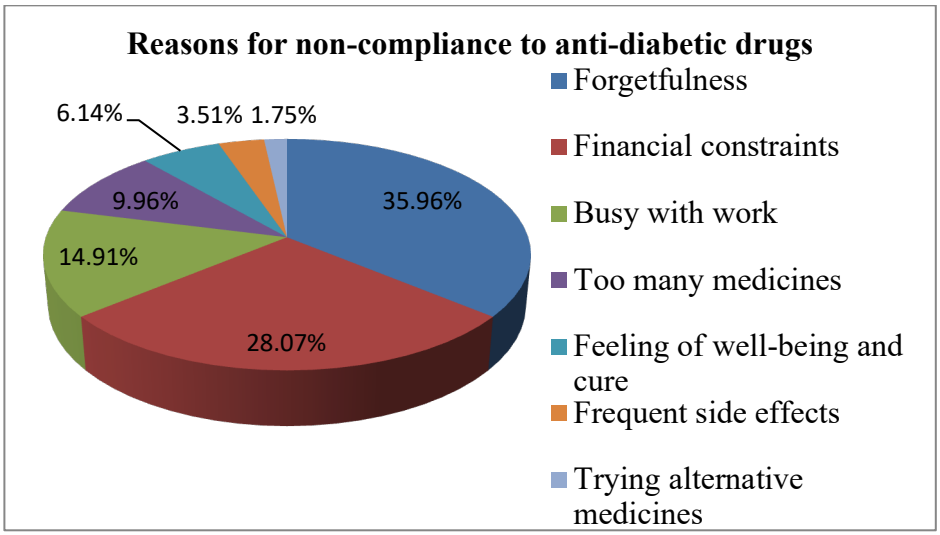


Figure 1: Type of Medication with compliant and non-compliant with drug therapy

The most common reason behind the non-compliance with the drugs was found to be forgetfulness (41.396%), which was followed by financial constraints. busy with work, 17 (14.91%), and too many medicines being prescribed, 11(9.565%). A smaller proportion (7.14%) of patients also mentioned a feeling of well-being and cure as one of the reasons behind their non-compliance [Table-2].

Table 2: Reasons for non-compliance to anti-diabetic drugs (n = 114)

Reasons	Number (%)
Forgetfulness	41(35.96)
Financial constraints	32(28.07)
Busy with work	17(14.91)
Too many medicines	11(9.65)
Feeling of well-being and cure	7(6.14)
Frequent side effects	4(3.51)
Trying alternative medicines	2(1.75)



Discussion

According to reports, compliance with chronic disease management, such as diabetes mellitus, is variable [13]. Expectedly, the patient's non-compliance with the prescribed hypoglycaemic medications could decrease the treatment effectiveness [14,15]. In the present study, an attempt was made to determine the relationship between various socio-demographic parameters and other patient characteristics and medication adherence as well as the causes of non-adherence as reported by patients, and it was found that the compliance rate for the anti-diabetic drugs was found to be 57.78%, while 42.22% were non-compliant. This, though 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 oral hypoglycaemic agents ranged from 36% to 93% [13]. In a study from Saudi Arabia, the overall prevalence of therapeutic compliance among the participants was found to be 32.1% [12]. In addition to the rate of compliance with the medications, it was also observed in the present study that only 36.29% and 27.03% of the study participants had followed the prescribed diet plan and the exercise schedule in the preceding week. Shobhana R et al. reported somewhat comparable findings: 19% compliance with exercise and 37% compliance with diet [7]. Jabbar et al. (2007) from Pakistan also reported compliance, with the diet and exercise schedules being 33% and 19%, respectively [16]. In the current study, both the univariate and binary logistic regression analyses revealed that drug therapy compliance decreased significantly with age. However, the compliance rate was significantly lower among men and illiterate people. But it had no significant association with marital status. Khan AR

et al. [12] and Kalyango JN et al. [17] discovered no significant association between age or marital status and anti-diabetic drug non-compliance. However, both of these studies [12, 17] reported the male sex and poor educational status to be significantly associated with non-compliance. The current study found that compliance was significantly lower among those with low monthly per capita incomes (Rs 1200). Shobhana R et al., from India, reported that non-compliance was higher among the lower socioeconomic groups [7]. Another study reported that those with a family income of less than the minimum wage (MMW) had shown 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 non-compliance with medications among those who 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 an increased odds of having poorly controlled diabetes, which indicated non-compliance [5]. Likewise, Gimenes HT et al. (2009) [19] made a similar observation. The results of the present study showed that the insulin alone regimen had significantly higher odds of non-compliance than the OHA alone regimen, while the combination of insulin and OHA had the highest odds of non-compliance among the anti-diabetic drugs. A multivariate analysis, which was done by Khattab M et al., also showed that patients receiving other forms of treatment were more likely to have poorly controlled diabetes than those who were only using oral anti-diabetic drugs. The use of insulin in conjunction with oral anti-diabetic medications has been linked to an increased risk of poor glycemic control [5]. In the present study, a significantly higher risk of non-compliance with drugs was found to be associated with patients who had no knowledge of the complications of diabetes. Wabe NT et al. (2011) also found that patients who were aware of diabetes complications had significantly higher drug adherence (p 0.001) [20]. In the present study, it was found that forgetfulness, followed by financial constraints, being very busy at work, being prescribed too many drugs, and a sense of being healthy and cured, were the most common causes of non-compliance with drugs. Pascal et al. (2012) from eastern Nigeria reported that the most common reason for non-adherence to medications by diabetic patients was financial constraints. Other common reasons include forgetfulness and feeling fine [21,22].

Limitations of the Study

The patients who weren't puerperialor preg nant when the interview took place (for fe male patients) The present study had some limitations. First of all, because the study was cross-sectional, a follow-up was not possible, which would have allowed for a case study of the non-compliance problem. Secondly, because patients self-reported their compliance, there was always a chance that it would be overstated. This was, however, somewhat minimised by the corroboration with the HbA1C level. Thirdly, conducting in-depth interviews or focus groups would have provided more information on the causes of the noncompliance from the patients' perspective than the quantitative aspect of the data could. However, this study has left scope for more research in these areas in the future.

Conclusions

It can be concluded from the present study that the compliance with 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 non-compliance. A more concerning finding was the link between noncompliance with drug regimens and a lack of knowledge

about diabetes complications, indicating the need for ongoing patient counselling and education about the fundamentals of type 2 diabetes. Financial constraints were one of the common reasons behind 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 for all.

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