Facilitators and Barriers of Treatment Compliance among Type 2 Diabetes Mellitus Patients Attending the Diabetes Clinic of a Tertiary Care Hospital, Kolkata: A Mixed-Methods Study

Abhipsa Dey¹, Baishakhi Paria², Moumita Mandal³, Aparajita Mondal⁴, Nabanita Bhattacharyya⁵, Mausumi Basu⁶

¹Senior Resident, ³Assistant Professor, ⁴Junior Resident, ⁶Professor and Head, Department of Community Medicine, IPGME & R and SSKM hospital, Kolkata, India

²Assistant Professor, Department of Community Medicine, Jalapiguri Medical College and Hospital, Jalpaiguri, India ⁵Principal, Infectious Diseases and Beleghata General Hospital, Kolkata, India

Correspondence: Dr. Mausumi Basu, E-mail : basu.mausumi544@gmail.com

Abstract:

Introduction: Type 2 diabetes mellitus is a disease of epidemic proportions and has emerged as a major healthcare problem. Compliance to medication plays a crucial role in achieving success in medical treatment and preventing complications. **Objectives:** The objective of this study was to assess the treatment compliance among the study participants and explore its perceived barriers and facilitators. Method: A descriptive crosssectional study was carried out using Morisky's Medication Adherence Scale (MMAS) among 308 type2 diabetes mellitus patients who were selected through systematic random sampling. Qualitative data was collected though in-depth interviews and were analysed by manual content analysis. Results: Out of the 308 study participants 47% were found to have high treatment compliance and 20% and 35% were found to have medium and low compliance, respectively. On binomial logistic regression, age, duration since diagnosis, family support and current treatment regimen were found to be significantly associated with treatment compliance. Multiple facilitators of compliance could be identified of which, self-awareness of disease, fear of complications and family support were most pronounced. Where asinability to purchase the medicines, forgetfulness, and lack of satisfaction with health services, were among the identified barriers of treatment compliance. **Conclusion:** High Compliance to diabetes medication was found among 47% of the study participants. Tailored interventions against the perceived barriers are necessary to promote compliance and improve glycaemic control.

Keywords: Mixed-methods study, Treatment compliance, Type 2 diabetes mellitus

Introduction:

Type 2 diabetes mellitus (T2DM) is a disease of epidemic proportions and has emerged as a major healthcare problem. It has been predicted that the absolute increase in the number of individuals with diabetes mellitus is expected to occur and the number of adults living with T2DM is estimated to increase from 463 million to 700 million by the year 2045.^[1]

India is called the "Diabetes Capital of the world" as it accounts for 17% of the total diabetes burden which is further expected to cross the 100million

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marks by 2030. India is also the largest contributor to regional mortality due to diabetes.^[2]

Type 2 Diabetes Mellitus can lead to multiple macrovascular (cardiovascular diseases, cerebrovascular diseases etc.) and microvascular complications (neuropathy, nephropathy etc.) and increase chances of premature mortality without optimum glycaemic control. Compliance to medication plays a crucial role in achieving success in medical treatment and preventing complications.^[3]

It is often found, given the lack of symptoms of the said disease and lack of awareness among individuals regarding the complications that may arise of it, the disease is often a subject of neglect and even slightest of inconvenience becomes a cause for non-persistence with treatment.^[4]

Multiple studies done in India have identified patient dissatisfaction, poor doctor-patient relationship and longer waiting time at healthcare facilities as important factors which increases the chances of non-compliance to medication.^[5] Lack of a flexible, patient-friendly healthcare system consisting of multiple drugs cause patients feeling overburdened by their treatment regimen and imposes an economic burden on them, which eventually leads them to resort to non-compliance.^[4] To identify and address the various facilitators and barriers of treatment compliance is of utmost concern and this study was done with the objective to explore them.

Method:

An explanatory sequential mixed-methods study was conducted in the diabetes clinic of Calcutta National Medical College and Hospital between October 2020 to October 2022. The quantitative part was a descriptive study of cross-sectional design, and the qualitative part was in the form of in-depth interviews. Adult T2DM patients who were diagnosed for at least 1 year were included in the study whereas pregnant, lactating women and seriously ill patients were excluded from the study.

Sample size : For the quantitative strand was calculated to be 308 (using Cochran formula, taking 76.2% prevalence of treatment compliance, obtained from a study by Chavan et al.^[5], 5% absolute precision and a non- response rate of 10%). For the qualitative strand, in-depth interviews were conducted till data saturation reached. Total 12 participants were interviewed.

Sampling technique:

Quantitative part:

As per the register of the clinic, the number of patients per day range between 50-60 patients, out of which on an average 30 patients fulfilled the inclusion criteria, thus a sampling interval of 10 was achieved. A complete list of the patients was taken from the register, a random number was selected (\leq 10 i.e., 7 in this study). Thus, the 7th patient of the register was the first participant. Then every 10th patient was chosen, each day by systematic random sampling, till the desired sample size was achieved. If any patient did not satisfy the inclusion criteria or fell in the exclusion criteria, the next patient was considered

Qualitative part:

Twelve patients (6 having good treatment compliance and 6 having poor treatment compliance) were selected purposively and interviewed till data saturation was achieved.

Methodology:

Quantitative component: Participants who provided a written informed consent were enrolled till desired sample size was achieved. The participants were interviewed with a using a predesigned, pre-tested, semi-structured schedule containing questions on socio-demographic and disease profile. Treatment compliance was assessed using **Moriskys Medication Adherence Scale** (**MMAS**)^[8] Permission was obtained to use this 8item, structured, treatment compliance scale. Those found to have high and medium compliance according to the scale were clubbed as having good treatment compliance and those with low compliance were considered as having poor compliance.

Qualitative component: For the qualitative component in-depth interviews were carried out with the help of an interview guide to explore the facilitators and barriers. Interviews were conducted with the help of a semi-structured interview guide till data saturation was achieved. The interviews commenced with open-ended questions with probing done wherever indicated to obtain detailed information and generate possible themes.

Data entry and statistical analysis:

All responses were entered and analysed using MS Excel software and IBM SPSS software version 25.0.^[6] Descriptive statistics were represented using frequency, percentages, mean and standard deviation. Chi-square test Followed by Binary Logistic regression analysis was performed for inferential statistics, to identify the factors associated with the outcome variable and p value of <0.05 was considered statistically significant. The in-dept interviews were transcribed verbatim from the audio recordings and manual content analysis was performed, generating themes and sub-themes which were then interpreted.

Ethical consideration:

Institutional ethics committee clearance and due written informed consent was obtained from each study participant. They were explained and assured about the confidentiality and anonymity of their information.

Operational definitions:

Treatment compliance: Medication compliance

(synonym: adherence) refers to the degree or extent of conformity to the recommendations about day-to day treatment by the provider with respect to the timing, dosage, and frequency. It may be defined as "the extent to which a patient acts in accordance with the prescribed interval, and dose of a dosing regimen."^[7]

Morisky 8-item Medication Adherence Questionnaire:

The Morisky Medication Adherence Scale (MMAS-8) is a structured diagnostic self-report measure that is used to assess medication adherence. It consists of 8 questions, each scored from 0 to 1.^[8] Total value was between 0-8.

A score less than 6 was considered as low compliance, 6-7 and 8 were considered medium and high treatment compliance respectively.

Glycaemic control: The glycaemic control was categorised as per ICMR (Indian Council of Medical Research) guidelines.^[9] Study participants were categorised as per any of the three criteria given in the Box-1 based on available reports (no older than 3 months preceding the interview date).

Results:

Quantitative results:

The mean age of the study participants was 57.6 ± 10.6 years out of which 54.2% were aged ≥ 60 years. There was a preponderance of female participants (59.4%) compared to males (40.6%). Majority of the study participants (72.5%) were unemployed and 30.5% of them were educated up to secondary level.

Over one-fourth of the study participants had type 2 diabetes for more than 10 years and more than half of them were on multiple oral hypoglycaemic

Criteria	Ideal	Satisfactory	Unsatisfactory
Fasting plasma glucose (mg/dl)	80-110	111-125	>125
2-hour post-prandial glucose (mg/dl)	120-140	141-180	>180
Glycated haemoglobin (gm%)	<7	<u>></u> 7-<8	<u>></u> 8

Box-1 : Criteria For Glycemic Control



Figure 1. Distribution of Study Participants according to Glycaemic Control (N=308)

agents. As per ICMR guidelines, only 42% of the study participants were found to have ideal glycaemic control whereas, 25% and 33% of them had satisfactory and unsatisfactory glycaemic control respectively. (Figure 1)

Forty-one percent of the study population had at least one other chronic comorbidity of which hypertension was the commonest comorbidity. Diabetic neuropathy was the commonest diagnosed complication, present among 68.9% of the study participants,

According to the Morisky Medication adherence Scale, only 47% of the participants were found to have high treatment compliance, while more than one-third (35%) of the participants had low compliance (Figure 2)

Good treatment compliance was found to be

Figure 2. Distribution of Study Participants according to Treatment Compliance. (N=308)



significantly higher among participants who were aged below 60 years, educated above secondary level, belonging to socioeconomic class I and II, employed and were diagnosed with T2DM for over 10 years. (Table 1)

On Binomial logistic regression, age, family support, duration since diagnosis and current treatment regimen were found to have a bearing on the participants treatment compliance. Older study participants (aOR= 9.14, 95% C.I. 5.57-17.53), those with the disease for over 10 years (aOR=2.03, 95% C.I. 1.38 -7.41), those with active family support (aOR=5.37, 95% C.I. 1.61-17.85) and those on multiple oral hypoglycaemic agents (OHA) for management of their disease (aOR=8.56, 95% C.I. 3.53-20.75) were found to have better compliance compared to their counterparts. (Table 2)

Qualitative results:

Facilitators in treatment compliance:

The following themes and subthemes were identified:

- Knowledge, which was further categorized into the following subthemes: a) Self-awareness and b) fear of complications of the disease
- Medication reminder system, further categorized into the following subthemes: a) Family support b) placing of medicines in favourable locations
- Adjustment of treatment regime as per requirement

Theme 1: Knowledge

Self-awareness of disease

According to the study participants, having knowledge about the disease condition and the dos and donts has helped them in being compliant to their treatment.

Participant 1, a 47-year-old male said "...I know I have type II diabetes. Since I got diagnosed, I have tried to know about this condition. I have also

Variables	Good Treatment	Poor Treatment	p value
	compliance, n (%)	compliance, n (%)	-
Gender			
Male	80 (64)	45 (36)	0.78
Female	120 (65.6)	63 (34.4)	
Marital status			
Married	125 (64.4)	69 (35.6)	0.8
Unmarried	75 (65.8)	39 (34.2)	
Education			
Secondary level and below	89 (57.4)	66 (42.6)	0.01
Above secondary level	111 (72.5)	42 (27.5)	
SES (As per Modified, B.G Prasad Scale, 2023)			
Class I & II	163 (75.5)	53 (24.5)	< 0.001
Class III &IV	37 (40.2)	55 (59.8)	
Employment status			
Employed	175 (78.5)	48 (21.5)	< 0.001
Unemployed	25 (29.4)	60 (70.6)	
Addictions			
Yes	85 (62.9)	50 (37.1)	0.52
No	115 (66.5)	58 (33.5)	
Duration since diagnosis (in years)			
<u><</u> 10	119 (60.1)	79 (39.9)	0.02
>10	81(73.6)	29 (26.4)	
BMI (as per WHO Asian classification)			
Underweight	7 (28)	18 (72)	< 0.001
Normal	72 (67.9)	32 (32.1)	
Overweight	74 (76.3)	23 (23.7)	
Obese	27 (33.8)	53 (66.2)	
Current treatment regimen			
Single OHA	44 (55)	36 (45)	0.01
Multiple OHA	117 (74.5)	40 (25.5)	
Insulin	23 (46.9)	26 (53.1)	
Insulin + OHA	15 (73)	7 (27)	
Family support			
Present	82 (60.7)	53 (39.3)	0.17
Absent	118 (68.2)	55 (31.8)	
Presence of other comorbidity			
Yes	113 (63.8)	64 (36.2)	0.6
No	87 (66.4)	44 (33.6)	
Complication due to diabetes			
Present	62 (68.9)	28 (31.1)	0.35
Absent	138 (63.3)	80 (36.7)	

Table 1: Distribution of Study Population according to Sociodemographic and Disease Profile (N= 308)

Table 2. Factors Associated with Treatment Compliance. (N= 308)					
Variables	p value*	AOR (95% C. I.)			
Age (in completed years)					
<u>></u> 60	<.01	9.14 (5.66-17.52)			
<60		1			
Education					
secondary level and below	0.71	0.87 (0,42-1.80)			
Above secondary level		1			
SES					
Lower class	0.41	10.59 (0.16-2.09)			
Upper class		1			
Employment status					
Unemployed	0.44	1.73 (0.42-1.72)			
Employed		1			
Duration since diagnosis (years)					
<u>></u> 10	0.03	2.02 (1.38-7.41)			
<10		1			
Family support					
Present	0.01	5.37 (1.61-17.58)			
Absent		1			
Current treatment regimen					
Multiple OHA	< 0.01	8.56 (3.53-20.75)			
Insulin	0.67	1.39 (0.30-6.50)			
Insulin + OHA	0.07	0.16 (0.84-46.15)			
Single OHA		1			

*Binary logistic regression, aOR: adjusted odds ratio, C. I: Confidence interval, SES: Socioeconomic status, OHA: Oral hypoglycaemic agents

asked questions to the doctor about the disease, such as what I should do, what I should not. I also know about the medicines and take them myself every day."

Fear of complications of the disease

Fear of the long-term complications of the disease emerged reiteratively among the study participants as an important factor for being adherent to their treatment regime.

Participant 5, a 59-year-old female said "One friend of mine who had uncontrolled sugar had skin disease on her legs which had to be cut off. Since then, I have been very careful with my

medication and diet. My blood sugar is now in control."

Theme 2: Medication reminder system

Family support •

Most of the participants were on multiple oral hypoglycaemic agents and forgetting to take them was a common problem identified among them. Being reminded to take medicines regularly by their family members in case of forgetfulness, helped them maintain good treatment compliance.

Participant 3, a 51-year-old female said "....I sometimes forget to take my medicines, but my granddaughter always reminds me and makes sure I take my medicines on time."

• Placement of medicines in favourable locations

Placing medicines in easy to spot locations was also a method adopted by participants to help them remember taking medications.

Participant 2, a 66-year-old male said, "… I have placed all my medicines on the centre of the dining table so that whenever I sit down to eat my food, I am automatically reminded to take them…"

Theme 3: Adjustment of regime as per requirement

Adjustment of medications by the treating physician as per the requirement of the patients was another facilitator of treatment complianceas per study participants.

Participant 4, a 45-year-old male said "I told the doctor I am unable to take so many medicines due to my work schedule, so he gave me combination medicines which decreased the number of medicines. Now it is easier for me."

Barriers in treatment compliance:

The following themes and subthemes were identified:

- Financial constraints, which was further categorised into the following subthemes: (a) Unavailability of medicines and (b) Inadequate funds to purchase medicines
- Maladjustment with treatment regime, which was further categorised into three subthemes:
 (a) Feeling overwhelmed by multiple medications (b) Forgetting to take medications, and (c) fear of side-effects
- lack of satisfaction with current treatment, further categorised into following sub-themes:

 (a) delayed service delivery at health care facility and (b) Preference of an alternate system of medication.

Theme 1 : Financial constraints

• Unavailability of medicines and inadequate funds to purchase medicines.

Participants stressed on the fact that the prescribed medications, apart from basic ones are often unavailable at the Government Health facilities which lead them to resort to out-ofpocket expenditure. They also admitted to their inability to report to the Hospital every month to collect medications which inadvertently have led to discontinuation in medication due lack of financial resources to purchase the same.

Participant 6, a 69-year-old female said," I was given two types of medications for my sugar, but it was not controlled by it. Then doctor sir added one more medication which was not available at the medicine counter. I bought the medication and took it for two months, but I am unable to buy it anymore, so I stopped taking it"

Participant 7, a 70-year-old male said,"I am 70 years old; how can I travel every month and stand in the queue every month to collect medication? I no sons to help me. Some months I come to collect medicines if my health permits otherwise I let go. I have no money to purchase medicine form outside..."

Theme 2 : Maladjustment with treatment regime

• Feeling overwhelmed and forgetting to take the multiple medications.

The study participants admitted to feeling burdened by the multiple medications that were prescribed to them for the control of diabetes. They felt the multitude of restrictions accompanied by the treatment regime has impacted their life and they have often found themselves unable to comply with it.

Participant 8, a 49-year-old female said, "… *I feel like I have been given more medications that the food I eat. How can I live like this?*"

Participant 10, a 47-year-old male said," ... as a frequent traveller it is very difficult for me to remember and take all the medicines with me. Taking medicines on time also becomes a challenge while travelling, thus I have often missed doses."

Fear of side effects •

Participants admitted that they are sceptical of the side-effects of the prescribed medications and have correlated multiple physical symptoms with them and often discontinued medications on that account.

Participant 9, a 53-year-old female said,"...whenever I take these medicines, I have severe gas and headache. I have been told there are side effects to these medications. Whenever I feel unwell, I skip the medicine..."

Theme 3 : Dissatisfaction with current treatment

Delayed services delivery at the Hospital

According to several participants, coming to the Hospital to avail services consumed entire day. This and resultant fear of wage-loss has led to patients opting for private consultations and medicine procurement, which they often are unable to keep up with.

Participant 11, a 41-year-old male said, "... I have to stand in line since early morning to meet the doctor, after which I again have to stand in line for hours to take medicines, for blood tests there is additional line. Coming to the hospital means I cannot go to work on that day and earn my daily wage..."

Preference of alternate system of medicine

A few participants cited their preference for AYUSH system of medicine instead of Allopathy. According to them Allopathic medicines have side effects on long term use and other medicines such as homeopathy give better results.

Participants 12, a 65-year-old male said, "I have always preferred Homeopathy and Ayurvedic medicines, but my sons force me to come here. My sugar is also not getting controlled by these medicines, so, I sometimes do not take them."

Discussion:

Diabetes Mellitus is a chronic disease which requires long term commitment to treatment regime. Non-compliance to treatment leads to inability to achieve optimum glycaemic control and development of life-threatening macro, microvascular complications, and mortality.

In this study nearly half of the study participants (47%) were found to have high treatment compliance, whereas 35% had low treatment compliance. Low treatment compliance was found to be present among all socio-economic classes, however, participants who were aged 60 years and above, those who had the disease for 10 years or more, those with family support and those who were on multiple oral hypoglycaemic agents were found to have significantly higher compliance to their diabetes medication. Contrarily in a study done in a teaching hospital in Nadia, West Bengal, by A Ghosh et al.^[11] Only 1.7% of the participants reported high treatment compliance whereas 60.7% were found to have low compliance to their medication.

In a study done by Arulmozhi S et al.^[12] in Puducherry, around 49.3% of the study participants were found to have high treatment compliance and those with good family support were found to have better compliance, which are similar to this study.

In another study done by Venkatesan M et al.^[13] in rural Tamil Nadu, prevalence of low compliance to diabetes medication was found to be 45.4%. Level of education, comorbidity status, satisfaction with government health facilities and doctor-patient relationship were found to be significantly associated with treatment compliance. On the other hand,

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patients age, duration of illness, illness perception and knowledge regarding disease were found to be the guiding factors for improved treatment compliance as reported in a study by Sharma D et al.^[14]

Results similar to this study was also obtained in a study done by Mishra Rakhi et al.^[15] in Uttarakhand, where 44% of the study participants were found to have good compliance and additionally treatment compliance was found to be associated with the quality of life of diabetic patients.

The qualitative component of this study explored the possible facilitators and barriers of treatment compliance among the study participants.

In this study unavailability of the costly oral hypoglycaemic agents and insulin and inadequate financial support to purchase them was a barrier which was repeatedly mentioned by the patients. Along with this fear of side effect of the multi-drug regimen, forgetfulness and dissatisfaction with the time-consuming service delivery at the health facility were identified as other contributory barriers. Whereas the awareness of the disease and its possible complications and family support were some of the identified facilitators of treatment compliance. In a study done by Murugan Venkatesan et al.^[13] Exploring the barriers in diabetes treatment compliance, similar themes emerged along with lack of transport facility to the health facility and inaccessible timing of health facility In a systematic review by Krishnamoorthy Yuvraj et al.^[5], evidence similar to this study was synthesized form 18 studies and lack of patients understanding of the disease and its complications, forgetfulness and misconception about the medications were found to be major barriers to treatment compliance, whereas patients self-awareness, positive peer influence, empathy from healthcare providers along with family support facilitated compliance to diabetes medication.

In another study by Divya S et al.^[16], factors such as illiteracy, economic problems, lack of information regarding prescribed medications, lack of awareness regarding regular medications were found to be the contributory factors of non-compliance, which is in line with the findings of this study.

In this study, along with the level of treatment compliance among the study participants, their perceived obstructions in achieving optimum compliance could be identified, which can help health care providers formulate interventions to mitigate these issues.

Conclusion:

Thirty-five percent of the study participants were found to have low treatment compliance in this study which was also reflected in their poor glycaemic control. With the ongoing epidemiological transition and progressive increase in the burden of type-2 diabetes and other non-communicable diseases, compliance to treatment remains a mainstay to achieve optimum glycaemic control and keep complications at bay. In this study awareness of the disease and its complications and family support were the identified facilitators, whereas forgetfulness, fear of side-effects of multiple medications and delayed service delivery at healthcare facilities were the most commonly mentioned barriers of treatment compliance. Based on these findings, tailored interventions such as optimisation of treatment regimen to meet the patients requirements and improvement in doctorpatient communication are necessary to promote compliance.

Declaration:

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Conflicts of interest: Nil

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