

ASSESSMENT OF THERAPEUTIC NON - COMPLIANCE AMONG TYPE 2 DIABETES MELLITUS PATIENTS

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ABSTRACT

Therapeutic Non - Compliance can be defined as the failure of a patient to correctly adhere to their prescribed healthcare plan. This includes missing medication doses, treatment schedules alteration or failing to follow recommended lifestyle changes. Therapeutic Non - Compliance can often lead to disease progression, frequent hospitalizations and increased healthcare cost of the patient. Diabetes mellitus (DM) is one of the most common metabolic disorder and is a major health problem of public. The role of Health Care Professionals (HCP) in educating the Diabetic patients regarding the disease management and medication adherence is very important. Medication Adherence of Diabetic patients can be improved by observing the patterns and factors influencing non adherence. This study aimed to assess the therapeutic non - compliance of Type 2 Diabetic Mellitus patients and to determine the predictors of non - compliance in Diabetic Patients. 500 Diabetic patients who were treated at a Tertiary Care Teaching Hospital of South Kerala were included in the study. Adherence levels were 28 %, 40 %, and 32 % for high, medium and poor adherence respectively. Results of this study showed that, the patients at the study site were moderately adherent to Anti-diabetic medications. This highlight the need for constant motivation and education at frequent intervals to ensure better adherence. The study could conclude that, the factors Age, Comorbid condition, knowledge about disease and medications, financial problem and number of drugs prescribed were statistically significant individually to therapeutic non - compliance.

KEYWORDS: Therapeutic Non - Compliance, Health Care Professionals, Type 2 Diabetic Mellitus, Medication Adherence, Anti - diabetic medications.

INTRODUCTION

Diabetes mellitus is a chronic, metabolic disease characterized by elevated blood glucose levels which further lead to over time serious damage to heart, blood vessels, eyes, kidneys and nerves. The most common type is Type 2 Diabetes mellitus, usually occur in adults, when the body becomes resistant to insulin or doesn't make sufficient insulin.^[1]

As per the World Health Organization, around 31.7 million individuals were affected by diabetes during the year 2000, which is expected to rise to 79.4 million by the year 2030.^[2] The prevalence of type 2 diabetes mellitus is increasing globally and 1.5 million deaths are

directly associated to diabetes each year. More than 50 % of people are unaware of their diabetic status and is leading to health complications if not detected and treated early.^[3] In India, an estimated 77 million people above the age of 18 years are suffering from type 2 diabetes mellitus and around 25 million are pre-diabetics.

Diabetic patients can live longer and healthier if the disease is detected and treated early. Proper patient counseling, interventions to promote a healthy lifestyle, patient education and timely treatment of complications can improve the health of diabetic patients. This study aimed to assess the therapeutic non - compliance among the type 2 Diabetic Mellitus Patients and to determine the

predictors of non-compliance of diabetic patients attending a tertiary care teaching hospital of South Kerala. Lower per capita monthly expenditure, irregular blood sugar monitoring, limited diabetes management instructions from health professionals, and those who did not receive family member's help to remember medications were more likely to report poor adherence compared with their counterparts.^[4]

According to the International Diabetes Federation (IDF), there are 463 million people living with Diabetes, with a prevalence of 9.3 % in people aged 20 – 79 years.^[5] Therapeutic Non-Compliance leads to a decrease in therapeutic effect of a drug, resulting in non-improvement of health and overburdening of health system.^[6] Non Compliance is generally associated with unfavorable outcomes like uncontrolled blood sugar and diabetes related complications.^[7]

MATERIALS AND METHODS

The study is a cross-sectional study conducted in the outpatient department of a Tertiary Care Teaching Hospital of South Kerala. The study period was July 2025 to May 2026.

ETHICAL APPROVAL

The study proposal was submitted and subsequently approved by the Institutional Ethical Committee of Al Azhar Medical College and Super speciality Hospital, Thodupuzha (IEC No : AAMC/IEC/2025/2-5).

STUDY CRITERIA

Inclusion Criteria

Patients above 18 years diagnosed with type 2 diabetes mellitus for at least six months and taking at least one anti diabetic medication.

Exclusion Criteria

Pregnant patients/severely ill patients/patients with altered mental status/any patient unable to give valid consent.

The patients who met the inclusion and exclusion criteria were enrolled in the study after obtaining the Informed

Consent Form (ICF) by clearly mentioning about the title, aim, duration, purpose, benefit and risk of the study to the study participants.

SOURCES OF DATA

➤ All the relevant data were collected from:

- Patient's case notes
- Patient's treatment chart
- Patient's laboratory data
- Patient/patient's care taker(s) interview
- Social demographic details of the patient
- Communication with other healthcare disciplines

Sample size

500 patients who were treated at the General Medicine Department of the study site taking at least one anti diabetic medications were included in the study.

Data collection

A suitable data collection form was prepared for the easy collection, documentation and analysis of data. The privacy and confidentiality of the data was protected during and after the study period.

For data collection and documentation, Patient's profile information which included information on patient's demographic details, presenting complaints, social habits, past medical/medication history, current medications details were collected after taking informed consent.

Morisky Medication Adherence questionnaire (Table 1) was used to assess medication adherence. The Morisky Medication Adherence Scale (MMAS-8) is a validated, 8-item self-reporting questionnaire used to measure medication-taking behavior and identify reasons for non-adherence.

Patients responded as "yes" or "no" to each of the questions asked. Based on the scores obtained:

- 0 was considered as high adherence
- 1 or 2 was considered as medium adherence
- > 2 was considered as low adherence

Table 1: Modified Morisky Adherence Scale.

Sl no	Questionnaire
1	Do you sometimes forget to take your medicine?
2	Thinking over the past 2 weeks, were there any days when you did not take your medicine?
3	Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?
4	When you travel or leave home, do you sometimes forget to bring along your medicines?
5	Did you take all your medicines yesterday
6	When you feel like your symptoms are under control, do you sometimes stop taking your medicines?
7	Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?
8	Do you have difficulty in remembering to take all your medicines?

Modified Morisky Medication Adherence Scale is a generic self-reported, medication-taking behavior scale with a scoring scheme of yes = 0 and no = 1. The items are summed to give a range of score from 0 to 8.

STATISTICAL ANALYSIS

Data collected was entered using Microsoft Excel and responses were expressed in percentage. P value less than 0.05 was considered to be statistically significant.

RESULTS

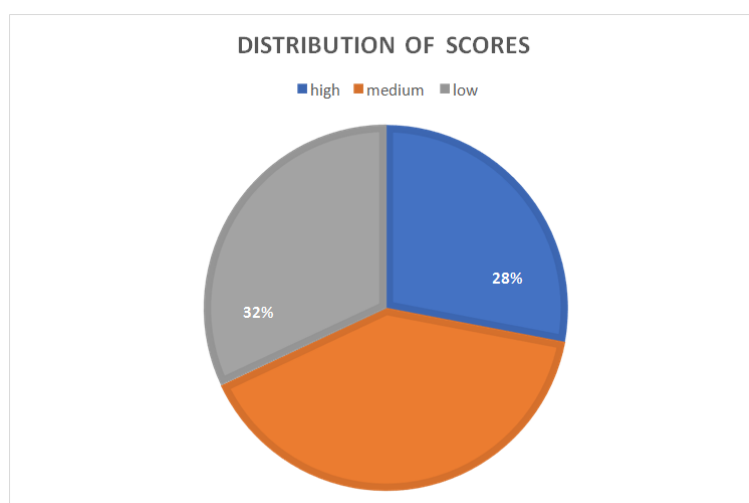
Table 2: Gender Wise Distribution of Study Participants.

Gender	Total no. of patients	Percentage (%)
Male	185	37
Female	315	63

A total of 500 patients were participated in this study and completed the questionnaire, out of which 63 % were females and 37 % were males. This showed a female predominance in the general medicine department at the study site during the study period. A female predominance among the study participants was also observed in the study conducted by Manobharathi M et al.

Table 3: Morisky Adherence Scale Of The Study Participants.

Distribution of Scores	Total no. of patients
High	140
Medium	200
Low	160



A total of 500 study participants participated in this study and completed the questionnaire of Modified Morisky Medication adherence scale. The study participant's responses to the Modified Morisky Medication Adherence scale showed that 40 % patients were

moderately adherent to anti diabetic treatment. This is similar to the study conducted by Kavitha S et al. 28 % of the study participants were highly adherent to Morisky Scale while 32 % of the study participants were less adherent to the Morisky scale.

Table 4: Predictors of Medication Non – Adherence.

Variables	Number	Percentage
Age		
≤ 60	237	47 %
>60	263	53 %
Comorbid Conditions		
Present Absent	310	62 %
	190	38 %
Financial Problems		
Present Absent	315	63 %
	185	37 %
Drugs prescribed number		
<3	200	40 %
≥3	300	60 %
Knowledge about disease and medications		
Patients with knowledge about disease and medications	195	39 %
Patients without knowledge about disease and medications	305	61 %

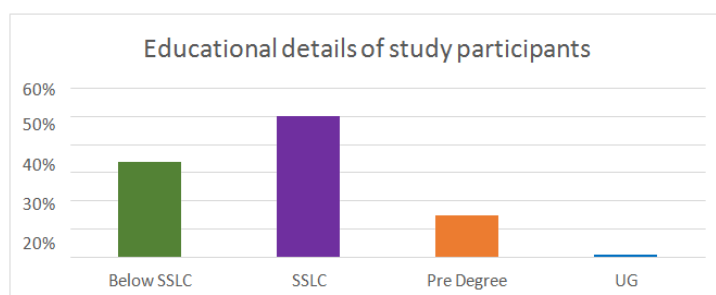
Among the 500 study participants enrolled in the study, majority 53 % were in the age group >60 years, only 47 % of the study participants were in the age group of

≤60 years. In the 500 study participants who participated in the study, majority (62 %) were having comorbid conditions, only 38 % of the study participants

were not having comorbid conditions. Majority of the study participants (63%) were having financial problems and only 37 % were not having financial problems. About 60 % of the study participants were prescribed with ≥ 3 drugs and only 40 % of the study participants were prescribed with < 3 drugs. Out of 500 study participants, majority (61 %) were not having knowledge about disease and medications, only 39 % of the study participants were having knowledge about disease and medications.

Table 5: Demographic Details Explaining The Educational Qualification of Study Participants.

Education	Number
Below SSLC	170
SSLC	250
Pre Degree	75
Under Graduation	5



Among the 500 study participants who participated in the study, majority (50 %) were having the educational qualification of SSLC, 34 % were having the educational qualification of below SSLC, 15 % were having the

educational qualification of pre degree and only 1 % were having the educational qualification of Under Graduation (U.G).

Table 6: Association of Non – compliance with Age.

Age	Compliant (%)	Non-Compliant (%)	Total
≤ 60	122 (51.47 %)	115 (48.5 %)	237
>60	63 (23.95 %)	200 (76.04 %)	263
Total	185	315	500

Among 500 patients enrolled in the study, in the age group ≤ 60 years, majority (51 %) were compliant and only 48.5 % were non – compliant. Considering the age

group >60 years, majority (76.04 %) were non – compliant and only 23.95 % were compliant.

Table 7: Association of Non – compliance with Comorbid Conditions.

Comorbid Conditions	Compliant (%)	Non-Compliant (%)	Total
Present	30 (9.6 %)	280 (90.3 %)	310
Absent	155 (81.57 %)	35 (18.42 %)	190
Total	185	315	500

Among the 500 study participants, out of the 310 patients with comorbid conditions, majority (90.3 %) were Non – compliant and only 9.6 % were compliant. Out of the 190

enrolled patients without comorbid conditions, majority 81.57 % were compliant and only 18.42 % were Non – Compliant.

Table 8: Association of Non – compliance with Financial Problems.

Financial Problems	Compliant (%)	Non – Compliant (%)	Total
Present	32 (10.1 %)	283 (89.84 %)	315
Absent	153 (82.70)	32 (17.29 %)	185
Total	185	315	500

In the 315 study participants with financial problems, majority (89.84 %) were Non – Compliant and only 10.1 % were compliant. In the 185 study participants without

financial problems, majority (82.70 % were compliant and only 17.29 % were Non – Compliant.

Table 9: Association of Non – compliance with drugs prescribed number.

Drugs Prescribed number	Compliant (%)	Non-Compliant (%)	Total
<3	127 (63.5 %)	73 (36.5 %)	200
≥3	58 (19.33 %)	242 (80.66 %)	300
Total	185	315	500

Among the 200 study participants prescribed with <3 drugs, majority (63.5 %) were compliant and only 36.5 % were Non – compliant. Among the 300 study participants prescribed with ≥3 drugs, majority (80.66 %) were Non – compliant and only 19.33 % were compliant. From the above table, it is clear that the study participants who were prescribed with more medications (≥3 drugs) is

having less compliance compared to the study participants who were prescribed with less number of medications (<3 drugs). This is due to the fact that, as the number of prescribed drugs increases, there is high chances for the patients for forgetfulness, confusion and reluctance to take the multiple prescribed medications.

Table 10: Association of Non - Compliance with knowledge about disease and medications.

Knowledge about disease and medications	Compliant (%)	Non - Compliant	Total
Patients with knowledge about disease and medications	169 (87.11 %)	25 (12.88 %)	194
Patients without knowledge about disease and medications	16 (5.22 %)	290 (94.77 %)	306
Total	185	315	500

Among the 194 study participants having knowledge about disease and medications, majority (87.11 %) were compliant and only 12.88 % were Non – Compliant. In the 306 study participants not having knowledge about disease and medications, majority (94.77 %) were Non – Compliant and only 5.22 % were compliant.

Table 11: Educational Qualification of Compliant Study Participants.

Education	Number (%)	Total
Below SSLC	15 (8.10 %)	170
SSLC	96 (51.89 %)	250
Pre Degree	70 (37.83 %)	75
UG	4 (2.16 %)	5
Total	185	500

In study participants, 4 out of 5 with UG educational qualification, 70 out of 75 with Pre Degree educational qualification, 96 out of 250 with SSLC educational qualification and 15 out of 170 with below SSLC educational qualification was found to be Compliant. Among the 185 Compliant Study participants, Majority (51.89 %) were having the SSLC educational qualification. About 37.83 % of the Compliant Study participants were having Pre Degree educational qualification. Around 8.10 % of the Compliant study participants were having below SSLC educational qualification. Minority of the Compliant Study Participants (only 2.16%) were having UG educational qualification.

Table 12: Association of Non – Compliance with The Selected Variables (Chi Square Test).

Sl. No	Variables	Compliance		Total	Chi square test
		Compliant	Non-compliant		
1	Age in years				$\chi^2=40.510$, $p<0.001^{***}$
	a) ≤ 60	122	115	237	
	b) >60	63	200	263	
2	Comorbid condition				$\chi^2=261.264$, $p<0.001^{***}$
	a) Absent	155	35	190	
	b) Present	30	280	310	
3	Financial problem				$\chi^2=263.131$, $p<0.001^{***}$
	a) Absent	153	32	185	
	b) Present	32	283	315	
4	Number of drugs prescribed				$\chi^2=100.422$, $p<0.001^{***}$
	a) < 3	127	73	200	
	b) ≥ 3	58	242	300	
5	Knowledge about Disease and Medication				$\chi^2=341.520$, $p<0.001^{***}$
	a) Patients with knowledge about disease and medication	16	290	306	
	b) Patients without knowledge about disease and medication	169	25	194	

The table 12 interprets that the Chi-square value is significant at 0.001 level. Therefore, it is revealed that, there is significant association between age and Non - Compliance. Majority of the study participants >60 years were found to be Non - Compliant. This shows that, the Therapeutic Non - Compliance was significantly high in higher age group.

Since the P-value < 0.001 for the factor Comorbid condition, there is significant association between the factor Comorbid condition and Non - Compliance. Majority of the study participants with comorbid conditions were Non - Compliant. This shows that, the Therapeutic Non - Compliance was significantly high in patients with comorbid conditions.

The table 12 shows a P value < 0.001 for the factor financial problem, which indicates that, there is significant association between financial problem and Non - Compliance. Majority of the study participants who were having financial problems were found to be Non - Compliant. Also, the study participants who were not having financial problems were Compliant in high number. This shows that, Non - Compliance is

significantly high in study participants with financial Problems.

As the P value < 0.001 for the factor number of drugs prescribed, it is clear that, there is significant association between the factor number of drugs prescribed and Therapeutic Non - Compliance. The Non - Compliant study participants who were prescribed with ≥ 3 drugs were higher than the Non - Compliant study participants who were prescribed with < 3 drugs. This shows that, the Non - Compliance is significantly high in study participants who were prescribed with ≥ 3 drugs.

Since the P value < 0.001 for the factor Knowledge about disease and medication, there is significant association between Knowledge about disease and medication and Therapeutic Non - Compliance. Only a smaller number of study participants without knowledge about disease and medication were found to be compliant. Majority of the study participants without knowledge about disease and medications were Non - Compliant. This reveals that, the Therapeutic Non - Compliance is significantly high in study participants who were not having knowledge about disease and medications.

Table 13: Comparison.

Factors	Beta	S.E.	Crude Odds ratio	Adjusted Odds Ratio	P Value	95% C.I. for EXP(B)	
						Lower	Upper
1. Age	-.304	.399	3.37	0.74	0.445	.338	1.611
2. Comorbid Conditions	-.152	1.362	41.33	0.90	0.911	.060	12.400
3. Financial Problems	-.106	1.368	4.28	0.90	0.938	.062	13.141
4. Drugs Prescribed Number	-1.379	.359	7.26	0.25	<0.001***	.125	.509
5. Knowledge about disease and medications	4.457	.543	0.008	86.21	<0.001***	29.755	249.780

The above table interprets binary logistic regression of the factors influencing Therapeutic Non.

- Compliance. Beta coefficient represents the rate with which predictors (factors influencing Non Compliance) change with outcome (Non - Compliance). Odds Ratio represents the influence of the binary variable on dependent variable. From the above table, it is clear that the factors Drugs prescribed number and Knowledge about disease & medication were highly significantly associated with Therapeutic Non - Compliance compared to the other 3 factors.

Table 14: Multiple Factors And Single Factor Association Details With Non - Compliance.

Associated factors	Number
Multiple factor	301(95.55 %)
Single factor	14 (4.44 %)
Total Non-Compliance patients	315

Among the 315 Non - Compliant study participants, majority (301 - 95.55 %) were having multiple reasons for Non - Compliance and only 14 (4.44 %) were having single reason for Non - Compliance.

DISCUSSION

Therapeutic Non - Compliance is a leading issue and is causing a great burden to health care system. In the developing countries like India, the factors like financial problem, lack of self-care, illiteracy and restricted access to health care system are the main causes of therapeutic non-compliance. In the present study, the factors Age, Comorbid condition, Financial problem, drugs prescribed number & knowledge about disease and medications were found significantly associated with therapeutic Non - Compliance. Similarly, in the study conducted by Shuvankar Mukherjee et al, it is observed that, compliance decreased significantly with increasing age, among males, illiterates and those with poor per capita monthly income.^[8] In the study conducted by Divya et al also, economic problems to buy medicines was one of the main factor for Non - Compliance. Similar kind of association between non - compliance and financial problems to buy medicines prescribed were reported in some other studies too.^[9,10] This may be due to the fact that many of the anti-diabetic drugs are expensive and are not available in the government sector.

Increase in number and dose of drugs which can cause “forgetfulness” in the older age group patients is one of the reason for non – compliance. In our study also, the factor drugs prescribed number was found to be significantly associated with Therapeutic Non – Compliance. A statistically significant association was found between non – compliance and frequent dosing & multiple drugs in a study done by Sharma T et al. However, in this study, there was no significant association found between non – compliance and increased dosage of drugs.

Good medication adherence in the study conducted in Mangaluru was found to be associated with age (<60 years), female gender, being married, while in a Puducherry study, it was associated with increasing age (>60 years) and longer duration of the disease.^[11,12] In a 2019 study conducted in Basra, medication adherence was found to be 65.4 %, while a study in Erbil, Iraq, using the Morisky Medication – adherence scale – 8, it was reported that, 40.3 % of the study participants had poor adherence.^[13,14] In the Erbil study, poor adherence was significantly associated with lower education levels and unemployment, highlighting the impact of sociodemographic factors on medication – taking behavior. The differences among these studies emphasize the importance of using less complicated regimens, using reminder systems (like setting an alarm on the phone) and continued support from the health system to improve adherence.

Limitation

This study was conducted at a single study site and this could affect the generalizability of the findings.

CONCLUSION

There is a need to identify the specific reasons for therapeutic non – compliance, so that more focused behavioral change strategies can be made for patients with Diabetes Mellitus. This becomes even more important even if the cultural factors are involved. Qualitative research methods can help to explore, which can finally help in better policy making, better treatment and positive therapeutic outcomes.

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CONFLICT OF INTEREST

None declared.

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