

PATIENTS WITH TYPE 2 DIABETES: ADHERENCE TO THERAPY – A CROSS-SECTIONAL OBSERVATION STUDY.

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Abstract Title

Patients with Type 2 Diabetes: Adherence to Therapy – A Cross-Sectional Observation Study.

Introduction

Diabetes has become the greatest global public health emergency of the century and is currently the ninth top cause of death worldwide. As a widespread condition that may be largely averted by making lifestyle improvements, type 2 diabetes (T2D) has been accurately termed a "global preventable pandemic" in recent years.

Glycaemic control is crucial for treating diabetes mellitus, and it is impacted by the patient's adherence to their prescription regimen. Non-adherence is a widespread and serious issue in both industrialised and developing nations. Research has indicated that patients comply inadequately with therapy for chronic illnesses. This paper aims to examine the prevalence of adherence and the factors that contribute to non-adherence.

Materials and Method

Over the course of 3 months, from Aug 2023 to October 2023, this cross-sectional study was carried out in the Outpatient department (OPD) of the department of Internal Medicine at a tertiary-care teaching hospital using Hill-Bone medication adherence scale to measure medication adherence. An Excel sheet from Microsoft was used to assemble the data and with the aid of SPSS 26.0, compiled data was analysed.

Results

A total of 186 diabetic patients were included. Participants' mean age ($\pm$ SD) was 57.85 ($\pm$ 10.33) years, with 84(45.2%) of them being female. The average duration of diabetes was 5 years ranging from 6 months to 27 years. Neuropathy was the most frequently reported diabetes-related complication among the 37.6% (70) of individuals. Out of 186, 16.1% had great adherence and 5.4% had poor adherence. Most individuals demonstrated good adherence (55.4%), followed by moderate adherence (23.1%). Inadequate follow-up 36(19.4%), financial status 42(22.6%), health beliefs 6(3.2%), side effects 9(4.8%), and forgetfulness 25(13.4%) are the primary obstacles to drug adherence.

Conclusion

The most significant element in predicting successful adherence, according to our research, is the socio-economic status and financial barrier. Nonetheless, other factors contribute to the issue of diabetes medication adherence. Patients must be informed about the condition and the significance of taking their drugs as prescribed to slow the disease's course and avoid complications.

Keywords

Diabetes type 2, Glycemic control, Knowledge, Medication adherence.

Title

Patients with Type 2 Diabetes: Adherence to Therapy – A Cross-Sectional Observation Study.

Introduction

Diabetes has become the greatest global public health emergency of the century and is currently the ninth top cause of death worldwide. The situation is worse in low- and middleincome nations like India, where the prevalence of diabetes has risen to epidemic levels.¹ Being a progressive condition, diabetes can cause major micro- and macrovascular problems in addition to the recently identified non-traditional consequences such as mental health issues, cancer, disability, and liver disease. The most dreaded result of complications from diabetes is death, and India has already seen one million fatalities from the disease thus far.¹⁻³

Diabetes not only increases mortality but also has a negative impact on mental and physical health. Nonetheless, vascular and musculoskeletal complications have a detrimental impact on DM patients' quality of life (QoL).⁴ As a widespread condition that may be largely averted by making lifestyle improvements, type 2 diabetes (T2D) has been accurately termed a "global preventable pandemic" in recent years. It is widely known that external risk factors such as smoking, being overweight or obese, eating processed foods, and leading a sedentary lifestyle can contribute to the development of insulin resistance and type 2 diabetes. Conversely, exercise and nutrition are inexpensive ways to ward against T2D and lower the risk of overall death in T2D patients.^{5,6}

Two of the most important factors in helping patients comprehend the treatment regimens are their awareness of and knowledge about their chronic condition and how to manage it. Previous research has shown that patients need to have a complete awareness of their medications, diet,

exercise routine, at-home glucose testing, foot care, and essential treatment adjustments to effectively self-manage their diabetes.⁷ Glycemic management is essential to halt the progression of deadly DM complications. Encouragement of patients to follow their doctors' advice, modify their lifestyles, and comply with treatment plans are all essential to achieving that aim.⁸ Research has indicated that patients comply inadequately with therapy for chronic illnesses.⁹

The World Health Organization defines adherence as “the extent to which a person’s behaviour-taking medication, following a diet, and/or executing lifestyle changes- corresponds with the agreed recommendations from a healthcare provider”.¹⁰ Healthcare practitioners have faced a significant challenge in managing diabetes because of nonadherence to therapy, which can happen at any point during the treatment process.¹¹ Several illnesses and polypharmacy further hamper medication adherence in older persons. Cultural traditions and the unequal distribution of healthcare providers across urban and rural communities hinder medication compliance. Non-adherence is also influenced by forgetfulness brought on by mental health conditions.¹² In low- and middle-income nations like India, which is also in the top three with the highest percentage of adult diabetics, continued nonadherence will impose a burden on the healthcare system.¹³

Glycaemic control is crucial for treating diabetes mellitus, and it is impacted by the patient's adherence to their prescription regimen. As a result, to obtain a successful management of diabetes, it is imperative to evaluate medication adherence.¹⁴ Low adherence to both pharmacological and non-pharmacological therapy has been seen in the majority of prior investigations on anti-DM drug adherence.¹⁵

Non-adherence is a widespread and serious issue in both industrialised and developing nations.¹⁶ This paper aims to examine the prevalence of adherence and factors that contribute to non-adherence.

Materials and Method

Over the course of 3 months, from Aug 2023 to October 2023, this cross-sectional study was carried out in the Outpatient department (OPD) of the department of Internal Medicine at a tertiary-care teaching hospital. This study comprised patients with type-2 Diabetes Mellitus who visited the outpatient clinic of S. S. Institute of Medical Sciences & Research Centre. Following evaluation for inclusion and exclusion criteria, patients were enrolled in the trial provided written informed consent.

Inclusion criteria

- Subjects who were on oral hypoglycemic drugs for type 2 diabetes mellitus
- Subjects of age above 18 years
- Subjects who have been taking medication for more than 6 months. **Exclusion**

criteria

- Subjects of age less than 18 years □ Newly diagnosed patients.

- Subjects who have been taking medication for less than 6 months □ Patients who were ill and required hospitalisation.
- Subjects who were taking other forms of medications (Ayurvedic and Homeopathic). □ Subjects who are not able to participate.

Using a pre-made questionnaire, the chosen patients were asked about their sociodemographic traits, income, length of drug use, and reasons for not taking their medications as prescribed. The socioeconomic classes adjusted by the Kuppaswamy scale in 2018 were used to categorize the study subjects. The nine-item, self-interviewable Hill-Bone medication adherence scale^{17,18} was used to measure medication adherence.

An Excel sheet from Microsoft was used to assemble the data and with the aid of SPSS 26.0, compiled data was analysed. We used percentage analysis for all categorical variables. Using the mean, standard deviation (SD), and chi-square test, quantitative variables were examined. To determine how significant the relationship was between the groups, the chi-square test was employed. A statistical significance threshold of less than 0.05 was applied.

Results

A total of 186 diabetic patients were included in the study who fulfilled the inclusion and exclusion criteria with informed consent provided. There are no dropouts as everyone has shown interest to participate in the study. The participants' mean age ($\pm$ SD) was 57.85 ($\pm$ 10.33) years, with 84(45.2%) of them being female. The average duration of diabetes was 5 years ranging from 6 months to 27 years. Of the patients, 61.3% (114) had a family history of diabetes, while the most prevalent co-morbidity ($n = 36$, 19.6%) was hypertension. Neuropathy was the most frequently reported diabetes-related complication among the 37.6% (70) of individuals.

Out of 186 diabetic patients enrolled in the trial, 16.1% had great adherence and 5.4% had poor adherence. Most individuals demonstrated good adherence (55.4%), followed by moderate adherence (23.1%). Inadequate follow-up 36(19.4%), financial status 42(22.6%), health beliefs 6(3.2%), side effects 9(4.8%), and forgetfulness 25(13.4%) are the primary obstacles to drug adherence.

Table 1: Age and gender distribution

		Age Group					Total
		36-45	46-55	56-65	66-75	>75	
Gender	Female	15	17	30	16	6	84
	Male	11	31	35	19	6	102
Total		26	48	65	35	12	186

Table 2: Demographic Data

		Participants (n)	Percentage (%)
Residence	Rural	74	39.8
	Urban	112	60.2
Education	Primary School	59	31.7
	High School	94	50.5
	Graduate	33	17.7
Socio-economic	Class I (upper)	3	1.6
	Class II (upper middle)	11	5.9
	Class III (lower middle)	64	34.4
	Class IV (upper lower)	73	39.2
	Class V (lower)	35	18.8
Marital status	Married	152	81.7
	Single	2	1.1
	Unmarried	3	1.6
	Widow	29	15.6
Family type	Joint Family	77	41.4
	Nuclear Family	109	58.6

Table 3: Demographic Factors related to medication adherence

		Excellent	Good	Moderate	Poor	Total	P-value
Age Group	36-45	4	16	5	1	26	0.774
	46-55	7	29	10	2	48	
	56-65	13	34	15	3	65	
	66-75	5	20	7	3	35	
	>75years	1	4	6	1	12	
Residence	Rural	11	41	16	6	74	0.584
	Urban	19	62	27	4	112	
Sex	Female	17	45	19	3	84	.451
	Male	13	58	24	7	102	
Education	Primary	13	34	8	4	59	.180
	High School	15	51	25	3	94	
	Graduate	2	18	10	3	33	
Socioeconomic	Class I	0	0	1	2	3	.005
	Class II	3	7	1	0	11	
	Class III	9	38	14	3	64	
	Class IV	13	41	16	3	73	
	Class V	5	17	11	2	35	

Duration of Disease	<1yr	0	5	2	0	7	.308
	2-5yrs	23	63	24	4	114	
	6-10yrs	5	31	13	4	53	
	>10yrs	2	4	4	2	12	

Table 4: Disease Factors related to medication adherence

		Excellent	Good	Moderate	Poor	Total	P-value
Family History	No	8	35	22	7	72	.021
	Yes	22	68	21	3	114	
Duration of Disease	< 1year	0	5	2	0	7	.308
	2-5yrs	23	63	24	4	114	
	6-10yrs	5	31	13	4	53	
	>10yrs	2	4	4	2	12	
Diabetic Diet	No	25	83	34	7	149	.830
	Yes	5	20	9	3	37	
Physical activity	No	21	75	26	8	130	.437
	Yes	9	28	17	2	56	
No of drugs	<3	22	84	31	9	146	.658
	>3	8	9	12	1	40	
Experience of side effects	No	4	30	9	4	47	.199
	Yes	26	73	34	6	139	
Counselling	No	20	68	25	6	119	.805
	Yes	10	35	18	4	67	

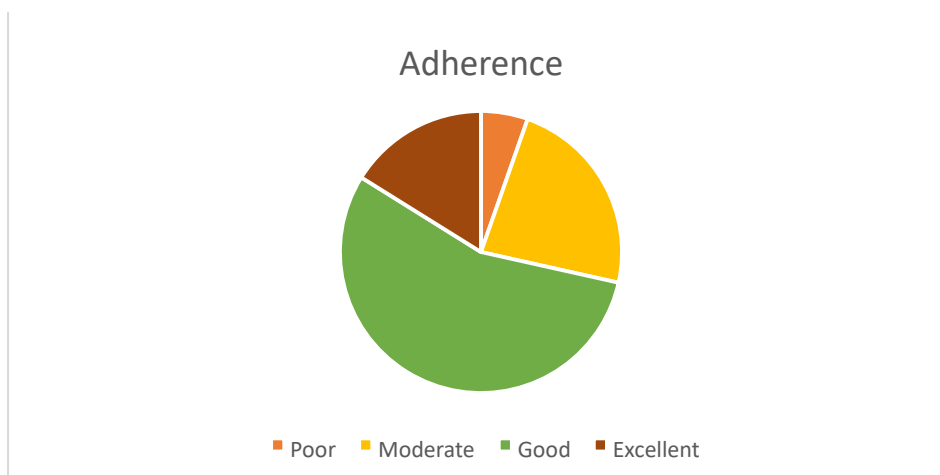


Figure 1: The degree of adherence with anti-diabetic medications.

Discussion

One of the main public health issues relating to diabetes is non-adherence to anti-diabetic medication, which can increase the disease's severity and hospitalization rates. 28.5% of the individuals in our research had poor to moderate adherence to anti-diabetes medications, which

can be correlated with the study done by Maheshwari M et al.¹⁷ where it was 6.7% poor and 27.9% had moderate adherence. Poor adherence to anti-diabetic treatment has been reported in studies from India and other regions of the world, with results ranging from 7% to 83.5%.^{4,7,8,11–16,19–23} The lack of a common, agreed criteria for adherence as well as the use of several adherence surveys may be the cause of this heterogeneity in the degree of adherence to anti-diabetic medication.

The age range of 46 to 75 accounted for the bulk of the patients. This can be connected with the findings produced by Maheshwari M et al.¹⁷ and is caused by increased resistance to insulin and decreased glucose absorption that happens with age owing to loss of muscle mass. Financial constraints were the most often mentioned reason given by the majority of participants for not taking drugs regularly. This was further proved by the positive correlation of medication adherence with socio-economic status (p-value – 0.05). Research carried out by Rathish et al.¹⁴ and Maheshwari M et al.¹⁷ in other regions of India also highlighted financial barriers as a factor contributing to pharmaceutical non-adherence. Inadequate follow-ups and forgetfulness are the other two major factors for non-adherence. A patient's forgetfulness is one of the patient-related variables contributing to non-adherence, and it may be strengthened by their doctor, who can counsel and educate them about diabetes and the significance of medication compliance. Other factors contributing to nonadherence to prescription regimens were high drug costs, limited drug availability, low income, ignorance of the significance of medications, and hectic job schedules.^{13,14,17,24–27}

Numerous studies conducted globally have demonstrated a range of characteristics linked to positive adherence to diabetes medication, including diabetes for less than five years²⁸; higher education level^{24,28}; female gender²⁹; living in an urban area²⁴; and single-drug regimen.²⁷ However, our investigation revealed no significant correlation between any of these characteristics and excellent adherence behaviour.

Our findings, which are consistent with the Gopalakrishna et al.³⁰ study, show that side effects account for 4.8% of the reason why patients adhere to their treatment regimens poorly. Studies carried out elsewhere also have revealed that non-adherence was caused by drug side effects.^{26,28,29,31} Weight gain, dyspepsia, giddiness, blackout, sweating and hypoglycaemia were among the negative effects the research participants encountered. Study participants did by R. Thapar et al.¹³ experienced gastrointestinal issues, weight gain, and hypoglycaemia-related symptoms, among other adverse effects.

Using the Hill bone medication adherence scale, the evaluation revealed that 16.1% had outstanding medication adherence, 23.1% had moderate, 55.4% had acceptable, and 5.4% had poor. This is consistent with the research done by Maheshwari M et al.¹⁷ and Tivet et al.³² Research conducted all over the world demonstrates the multifaceted and universal nature of the non-adherence problem. Poor adherence can result in early and more serious problems, which will put a financial cost on the patient and overload the healthcare system. In nations with low resources, this effect may be particularly noticeable.

Limitations

Our study's conclusions cannot be broadly applied because of the small sample size. The adherence assessment tool employed in our study, the Hill bone medication adherence scale, has not been proven to be reliable in the Indian community. The unbalanced age distribution of

the population—the majority of whom are between the ages of 46 and 75—is the study's other shortcoming. The basic explanation is that the risk of developing diabetes rises with age.

Conclusions

The most significant element in predicting successful adherence, according to our research, is the socio-economic status and financial barrier. Nonetheless, other factors contribute to the issue of diabetes medication adherence. In diabetes, noncompliance with treatment usually results in inadequate blood glucose regulation, a reduced standard of living, and earlier mortality. Patients must be informed about the condition and the significance of taking their drugs as prescribed to slow the disease's course and avoid complications. To improve medication adherence in patients with Type 2 Diabetes mellitus, educational treatments including the teach-back technique, the ask-educate-ask strategy, and motivational interviewing should be considered.

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