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Medication Adherence in Patients with Type 2 Diabetes Mellitus Treated at Outpatient Department in Government Tertiary Care Centre in North India

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Abstract:-

Introduction:-

Diabetes mellitus is a chronic progressive disease characterized by numerous health complications. Medication adherence is an important determinant of therapeutic outcome. Oral hypoglycemic agents (OHAs) are the major treatment for people with type 2 diabetes mellitus (DM2). However, non-adherence to OHAs remains are one of the main reasons for poor glycemic control. Medication nonadherence in patients with chronic diseases, particularly in type 2 diabetes mellitus (T2DM) with comorbidity, has continued to be the cause of treatment failure. The current study assessed the level of medication adherence in T2DM patients with and without Hypertension.

Methods:-

A total of 350 patients were enrolled from the Department of Internal Medicine at King George's Medical University (KGMU), Lucknow

according to the American Diabetes Association (ADA) guidelines. Both male and female patients of age between 35-75 years, on oral hypoglycemic agents (OHA) excluding insulin, providing written included consent were in study. An institutional-based descriptive cross-sectional study was conducted among T2DM patients. The seven item Morisky Medication Adherence Scale questionaire was used assess the level to of adherence. The questionaire had 7 questions with 4 responses each and a 4 point Likert scale was used for each questions .The response "never" will be given a score of 4, "sometimes" (one to four times per month) score of 3, "often" (more than five times per month) score of 2 and "always" a score of 1. According to the scoring it was further divided into low, medium and high adherent. On each visit to the OPD the questionaire was provided to the patients.

Results:-

A total of 60 patients were lost to follow-up, resulting in 290 patients having diabetes further completed the study. About 10.7% had a high adherence, 34.5% had a medium adherence, and 54.8% had a low adherence level respectively. Adherence score level was positively and significantly correlated with age (P< 0.05). Similarly significant correlation was found between adherence level with gender (P< 0.05). However adherence level was not significantly associated with duration of diabetes (P>0.05) and number of hypoglycemic medications (P>0.05). A logistic regression model was used to identify predictors of the level of medication adherence and glycemic control. P < 0.05 at 95% confidence interval (CI) was statistically significant.

Conclusion:-

The majority of patients having diabetes in this study had low adherence level. The three main factors which contributed to non-adherence to medication are non-adherence to regular follow-up visit in diabetes OPD, non-adherence to healthy diet, and non-adherence of instructions on taking medication. The current study concluded that medication adherence was low and significantly associated with poor glycemic control. Number of medical conditions and medications were found to be associated with medication adherence. Management interventions of T2DM patients with comorbidity should focus on the improvement of medication adherence.

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. Diabetes mellitus (DM) continues to be a public health problem worldwide with the number of people presenting with diabetes estimated to be 783 million by 2045 [1]. The prevalence of T2DM in developing countries has increased rapidly worldwide and accounts for more than 95% of diabetes cases [2]. The majority (three-fourths) of the diabetes patients are living in low and middle-income countries [3]. 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 [4, 5]. This makes diabetes among the most common public health threats & non communicable disease. A poor and inadequate glycemic 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 [6]. 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 [7]. However, implementing protocols to control the disease and introducing methods to improve the adherence to treatments and self-management by patients will help achieving optimal glycemic control through strict compliance to medications, diet, and lifestyle modifications and hence reducing the chronic complications and the risk of death [19, 20, 21, 22]. Poor knowledge about medication and treatment goals, perceptions about the medication, complexity of regimens, side effects, and cost are the main causes of nonadherence to medication [8, 9]. Evidences suggests that non-adherence to diabetes medications affects glycemic control that leads to complications associated with diabetes progression, hospitalizations, morbidity and mortality which further increases the risk of negative consequences and high medical costs with considerable direct and indirect problems to the

sustainability of the healthcare system [10 , 11 , 12 , 13 , 14 , 15] . Also poor access to drugs, the high costs of drugs, an unequal distribution of the health care providers between the urban and the rural areas and one of the barriers which further hamper the self-care activities in developing countries such as in India [16 ,17 ,18]. The purpose of this study was to assess patient adherence to oral hypoglycemic medications and factors contributing to non-adherence in patients with Type 2 diabetes. The non-compliance was higher among the lower socio-economic groups.

<u>Materials & Methods:-</u>This descriptive cross-sectional study was conducted in the diabetic outpatient department (OPD) of internal medicine department at King George's Medical University (KGMU), Lucknow, India during the period from June 2021 to March 2023. The study protocol was approved by the Institutional ethics committee of the institution and informed consents were obtained from all the study participants who were patients attending the diabetic clinic of this institution during the study period &suffering from type 2 diabetes.

The study participants were selected on the basis of the following:-

Inclusion Criteria:

- 1) Subjects having diabetes and hypertension and diagnosed according to IDF guidelines.
- 2) Patients with type 2 diabetes and on oral hypoglycemic medications.
- 3) The patients who were aged 20 years or above.
- 4) The patients who were non-pregnant or non-puerperal at the time of the interview (for female patients).
- 5) Those who gave informed consents to participate in the study.

The patients who were excluded from the study:-

Exclusion criteria:-

- 1) Subjects having any CNS disease or psychiatric disorder.
- 2) Subjects on insulin therapy.
- 3) Patients not willing to give consent.

The diabetic OPD clinic runs from Tuesday to Friday i.e. 4 days per week. Both new and follow up patients having diabetes were screened& were recruited according to the inclusion & exclusion criteria respectively & it took approximately 2 years to complete the sample size. Patients who were included were all having T2DM and were over 20 years of age, with ongoing treatment. Each participant was interviewed by using a pre-designed, pre-tested, structured enrollment form 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 associated complications of diabetes. The level of Medication adherence was assessed by using a structured, pretested & validated Medication Compliance Questionnaire (MCQ) that was developed by using the Morisky self-reporting scale[12], Hill—Bone Compliance to High Blood Pressure Therapy Scale[13] and Morisky Medication Adherence Scale[14] the adherence. A 4-point Likert scale was appointed for each question: none of the time = 4; sometimes (one to four times per month) = 3; most of the time (more than five times per month or more than two times per week) = 2; all the time = 1. The total

scores were added for each patient. The scores may range from 7 (minimum) to 28 (maximum). Based on the scoring system used in the Morisky Medication Adherence Scale, a total score of 27 and above was considered adherent [14]. It highlights forgetfulness of medication, measures medication use, stops to take medication when feel worse, forget to take medication when travel or go out of home, measures medication use in yesterday, stops to take medication when feel better, feeling dissatisfaction due to daily commitment to take hypoglycemic medicine, facing difficulties to remember to take all medications.

The maximum score 27 and 28 represents high adherence, 23-26 represents medium adherence and below 22 represents low adherence

Statistical Analysis:- For qualitative data (gender, education level, marital status, duration of the disease, comorbidities, drug regimen, income, smoking, committed to follow-up, relationship with prescribers, suffering from side effects, adherence level), frequency and percent were used. Chi-square test was used to test the correlation between adherence and non-adherence and also to compare the level of adherence with difference in age, education level, marital status, disease duration, drug regimen, monthly income, and smoking with. Regression analysis was used to find the possible factors for non-adherence. The data analysis was carried out by using Statistical Package for Social Science (SPSS) for WindowsIBM SPSS Statistics 28.0.1 version 2022. The categorical data such as for qualitative data (gender, education level, marital status, duration of the disease, comorbidities, drug regimen, income, smoking, committed to follow-up, relationship with prescribers, suffering from side effects, adherence level), frequency and percent were used. sex, race, age, duration of disease, body mass index, family history, comorbidities, and level of education are presented as frequency and percentage. Chi-square test was used to Statistical significance was accepted at the 95% confidence level. Binary logistic regression analysis was conducted to identify factors associated with non-adherence, while adjusting for covariates. Variables analysis with a P-value < 0.05 was included in the logistic regression model analysis by using the stepwise backward likelihood ratio method to identify factors that could significantly affect non-adherence. Regression analysis was used to find the possible factors for non-adherence. P < 0.05 was considered statistically significant for this study.

Results:-A total of 250 patients between 20 and 75 years of age with diabetes, were included in the study, the majority (65.9%) were female. Regarding level of education, 50% were college graduate and above, 22% are high school, 19% are primary school, and only 9% are secondary school graduates. Regarding marital status, 211 (72.8%) were married, 48 (16.6%) single, 22 (7.6%) widow, and 9 (3%) divorced.

Duration of the disease ranges: 115 (40%) from 5 years or less, 67 (23%) from 6 to 10 years, 43 (15%) from 11 to 15 years, 38 (13%) from 16 to 20 years, 27 (9%) for more than 20 years.

Of the total, 149 (51%) have other comorbidities while 141 (49%) not have other comorbidities. These morbidities include 73 (49%) hypertension, 42 (28%) dyslipidemia, 9 (6%) heart disease, and 25 (17%) for others.

Most of the patients 81 (27.9%) take more than three drug, 75 (25.9%) take three drugs, 71 (24.5%) take one drug, and 63 (21.7%) take tow drug.

Majority 99 (34.1%) have 5000-10000 SR income, 85(29.3%) have<5000 SR income, 54 (18.6%) have more than 15000 SR income, 52 (18%) have 11000-15000 SR income.

In most of the patients with diabetes, 256 (88%) were non -smoker, 17 (6%) were smoker, 17 (6%) were previous smokers.

The majority of patients 158 (54.5%) were always committed to follow-up in the clinic, where 132 (45.5%) not committed to follow-up.

For those who are not committed, the reasons behind non commitment are, they did not think it is necessary to follow up 54 (40.8%), forgot the appointment 33 (25.1%), non availability of transport 26 (20%), and 19 (14.1%) specified other reasons.

Of the total, 107 (37%) of patients stated that they follow the doctor instruction while 183 (63%) were not.

Furthermore, 240 (82.8%) of patients with diabetes said that the drug information was enough to them, where 50 (17.2%) said that it was not enough.

Nevertheless, most (53, 40.8%) of the patients did not think it necessary for follow-up, where others forgot the appointment (30, 25%), non-availability of transport (24, 20%), and (13, 14.2%) specified other reasons.

Of the total, 107 (37%) of patients stated that they follow the doctor instruction, while 183 (63%) were not.

Most of the patients (191, 66%) not suffer from drug side effect were (99, 34%) suffered from side effect.

<u>Adherence:</u> Adherence level was obtained according to Morisky scale, Table 1 shows classification of patients according to adherence level.

Table 2 shows the classification of patients' age groups with different adherence level.

Comparison education level based on adherence level shown in Table 3.

Comparison of patients' adherence according to marital status, drug regimens, smoking status are shown in Tables 4-6, respectively.

Factors that can be directly related to non-adherence are shown in Table 7.

Discussion:- The results of the present study show that among the participants, 159 patients (54.8%) had low adherence, 100 patients (34.5%) had medium adherence, and only 31 patients (10.7%) had a high adherence. Our results are inconsistent with the results of Shaimol et al [23] who studied the adherence of 400 diabetic patients using MMAS, they found that the least percentages of patients (21.8%) have high adherence, 35.3% have medium adherence, 43% have low adherence. In another earlier study by Heissam et al [24] conducted in 376 patients, using the measure treatment adherence scale, they found that 98 (26.1%) have high adherence level, 180 (47.9%) have fair adherence level, and 99 (26%) have poor adherence level. However, the results are not in agreement with the results of other researchers; according Jamous et al [25] out of 130 patients there were 50 patients (38.5%) had high adherence, 58 (44.6%) had medium adherence, and 22 (16.9%) had low adherence rate. Also, Fadare et al. [26] conducted a study on 129 patients and classified patients as good, medium, and poor for 52 (40.6%), 42 (32.8%), and 34 (26.6%) patients, respectively. This difference in results of adherence level may be attributed to the differences in awareness about the importance of adherence to medication and may be also there are differences in strategies in different to improve adherence in different countries. The current study also noted that patients with higher age (53.6 years) found to have significant (P < 0.05) high level of adherence to medications than patients with lower age (43 years). This result is inconsistent with what was found in Fadare et al. study [26] which shows no significant difference in terms of adherence with different age groups (P > 0.05), and the study by Arifulla et al. [27] in a total of 132 patients they found no significant difference in adherence with regard to age (P > 0.05). Nevertheless, in the study by Gelaw et al [28] a total of 270 patients were interviewed, and they reported different result as the researchers found increase in age seemed to have statistically significant influence (P < 0.05) on respondents'

tendencies to have good adherence. This difference in results may be due to the good supportive social relationship in our local society that provide special care for elderly family members and care for their medicines and their adherence to medication.

Table 1:- Adherence Level

Level of adherence	Frequency (%)
Low adherence	159 (54.8)
Medium adherence	100 (34.5)
High adherence	31 (10.7)
Total	290 (100.0)

Table 2:- Comparison of age based on adherence

Level Of	Mean of age	Lower bound	Upper bound	P- Value
adherence				
Low adherence	43.0063	40.6663	45.3464	
Medium	49.9000	46.9654	52.8346	0.00
adherence				
High adherence	53.6667	47.8542	59.4791	
Total	46.5104	44.7235	48.2973	

Table 3:- Comparison of adherence level based on education level

Education Level	Adherence Low	Adherence Medium	Adherence High	Total %	P-value
Primary	13.2	23	35.5	19	0.017
Intermediate	7.5	11	9.7	9	
High	22.0	20	29	22.1	
College graduate & above	57.2	46	25.8	50	
Total count	159	100	31	290	

The result of this study shows that there is a significant difference (P < 0.05) between different level of education in terms of adherence. Patients have good adherence level are 35.5% with primary education, 9.7% have intermediate education, 29.0% high school graduates, 25.8% are college graduate and above. College graduates patients have significantly low adherence level compared to primary education. This result is inconsistent with results by other researchers. Shaimol et al.[23] found that graduated patients have high adherence level. Fadare et al. [26] found no significant difference (P > 0.05) between different level of education regarding adherence. Arifulla et al.[27] also found no significant difference (P > 0.05) between different levels of education in terms of adherence. Gelaw et al.[28] found similar results. Although it is expected that patients with higher .lf level of education adhere better to their medication, the

cause of these different results may be due to that adherence as an attitude it is linked to people different perceptions rather than their education level.

Furthermore, the results show that married patients have significantly (P < 0.05) higher adherence state than non - married. This result is similar with what was reported by Gelaw et al. [28] where they found marital status significantly (P < 0.05) higher rate of therapeutic adherence (48.6%) than single, widowed, or divorced ones (21.9%). However, different results found by Khan et al. [29] studies show different results where they found no significant (P > 0.05) impact of marital status on patient adherence. The finding that married more adhere to medication is logic because patients may have help, care, and support from a spouse and family.

Table 4:- Comparison of marital status based on adherence levels

Marital Status	Adherence Low	Adherence Medium	Adherence High	Total %	P-value
Single	21.4	12	6.5	16.6	0.016
Married	67.3	81	74.2	72.8	
Widow	3.8	3	0.0	3.1	
Divorced	7.5	4	19.4	7.6	
Total count	159	100	31	290	

Table 5:- Comparison of drug regimen based on adherence levels

Drug	Adherence	Adherence	Adherence	Total %	P-value
Regimen	Low	Medium	High		
One drug	25.8	26	12.9	24.5	0.224
Two drug	21.4	23	19.4	21.7	
Three drug	28.9	18	35.5	25.9	
More than 3	23.9	33	32.3	27.9	
drug					
Total Count	159	100	31	290	

Table 6:- Comparison of smoking status based on adherence levels

Smoking	Adherence Low	Adherence Medium	Adherence High	Total %	P-value
No	92.7	92.5	100	93.4	0.304
Yes	7.3	7.5	0.0	6.6	
Total Count	150	93	30	273	

In the current study, there is no significant difference (P > 0.05) between number of drug regimen in terms of adherence. Similar results found in different studies. Donnan et al.[30] found significant (P < 0.05) linear trends of poorer adherence with each increase in the daily number of tablets taken. Wabe et al.[31] studied 384 patients and also found multiple drug

therapy in 75 (18.3%) of patients is one of the factors identified by patients as underpinning non-adherence.

This study shows that there is no significant difference (P > 0.05) between smokers and non-smokers in terms of adherence. This result is inconsistent with the narrative review by Tiktin et al. [32] in which they review published articles in medline. This review concluded that medication adherence is influenced by complex and multifactorial issues, which include smoking. This difference in result may be due to the small number of smokers in this study. Regarding factors contribute to non-adherence, there are three main factors may contribute to non-adherence to medication: Non-adherence to regular follow-up in diabetes clinic (odds ratio [OR] = 2.818, confidence interval [CI] = 1.697-4.682), non-adherence to healthy diet (OR = 2.823, CI = 1.676-4.756), and non-adherence to instruction to take medication (OR = 2.050, CI = 1.016-4.137). Similar results reported by another study by Khan et al. [29] in which they found the factors associated significantly with non-compliance are irregularity of follow-up (OR = 8.41, CI = 4.90-11.92) and non-adherence to drug prescription (OR = 4.55, CI = 3.54-5.56). However, the same study [29] concluded that there is no significant difference (P > 0.05) in terms of adherence to healthy diet with regard to adherence to oral hypoglycemic medications.

Conclusions:- Results obtained in this study can be summarized in the following points:-

- Majority of patients have low adherence scores, have duration of diabetes from 5 years or less, take more than three medications, have monthly income of 5000-10000 SR, and were nonsmokers.
- There is no significant difference term of adherence between different disease duration, number of drug regimen, smokers, and non-smoker.
- About half of the patients have comorbidities, and there is no significant difference between patients with or without comorbidities in term of adherence. The most important factors contribute to non-adherence to medication are non-adherence to regular follow-up in diabetes clinic (OR = 2.818, CI = 1.697-4.682), non-adherence to healthy diet (OR = 2.823, CI = 1.676-4.756), and non-adherence to instruction to take medication (OR = 2.050, CI = 1.016-4.137)

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