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Original Article

Assessment of medication adherence among type 2 diabetes mellitus patients: A cross-sectional study.

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Abstract Background

Medication adherence is a critical component in the management of type 2 diabetes mellitus (T2DM), directly influencing glycemic control and the risk of complications. However, adherence remains suboptimal in many settings, particularly in low- and middle-income countries, such as India.

Objective

To assess the level of medication adherence among T2DM patients attending a tertiary care hospital in South Odisha and identify key socio-demographic and clinical factors associated with adherence.

Methods

A cross-sectional observational study was conducted from August to October 2023 at MKCG Medical College and Hospital, Berhampur, involving 81 adult patients with type 2 diabetes mellitus (T2DM) who had been on pharmacotherapy for at least six months. Data were collected using a structured case record form and the Morisky Medication Adherence Scale (MMAS-8). Patients scoring ≥6 on MMAS-8 were categorized as adherent, and those scoring <6 as non-adherent. Associations between adherence and various factors were analyzed using chi-square tests and odds ratios.

Results

Among 81 patients, 57 were male (70.4%) and 24 were female (29.6%), with a mean age of 51.07 ± 11.08 years. Overall, 29.6% were adherent while 70.4% were non-adherent. Significant associations with adherence were observed for younger age <60 years (OR 5.09; 95% CI 1.32–19.6; p=0.008), literacy (OR 3.35; 95% CI 1.19–9.42; p=0.02), working lifestyle (OR 3.67; 95% CI 1.21–11.12; p=0.02), regular exercise (OR 2.97; 95% CI 1.02–8.63; p=0.04), and simpler therapy (\leq 2 drugs) (OR 6.69; 95% CI 1.66–26.9; p=0.002). Gender and treatment duration showed no significant association.

Conclusion

Medication adherence among T2DM patients in this setting was alarmingly low. Key determinants included age, education, lifestyle, physical activity, and complexity of therapy.

Recommendation

Interventions focusing on health literacy, lifestyle counseling, and simplified pharmacotherapy are urgently needed to improve adherence and outcomes in diabetes care.

Keywords: Type 2 diabetes mellitus, medication adherence, Morisky Medication Adherence Scale—8 Item (MMAS-8), polypharmacy, lifestyle factors, and health literacy.

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Introduction

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia, leading to serious complications affecting the heart, blood vessels,

eyes, kidneys, and nerves. Globally, the prevalence of diabetes has risen dramatically – from 108 million adults in 1980 to about 422 million in 2014 – and diabetes was directly responsible for roughly 1.5 million deaths in



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Study Population

The study population consisted of adult patients aged 18 years and above of either gender with a confirmed diagnosis of type 2 diabetes mellitus (T2DM) who had been receiving anti-diabetic pharmacotherapy for a minimum duration of six months. Patients were recruited consecutively from the hospital's outpatient department (OPD), and only those who fulfilled all inclusion criteria and provided voluntary, informed consent were enrolled. Patients aged below 18 years, pregnant women, individuals with major psychiatric illnesses or cognitive impairment, and those in acute emergency conditions were excluded from participation.

Sample Size

The minimum required sample size was estimated for a single proportion using the formula

 $n = (Z_1 - \alpha/2^2 \times p(1-p)) / d^2$,

assuming a two-sided 95% confidence level (Z=1.96), an expected adherence prevalence p=0.30 based on prior Indian hospital studies, and an absolute precision d=0.10. Substituting the values:

 $n = (1.96^2 \times 0.30 \times 0.70) \; / \; (0.10)^2 = (3.8416 \times 0.21) \; / \; 0.01 \approx 80.7.$

Thus, a minimum of 81 participants was required, and the study successfully enrolled 81 eligible T2DM patients within the three-month recruitment window, thereby meeting the calculated sample size. To minimize bias, consecutive eligible patients were recruited, ensuring representativeness and reducing selection bias.

Data Collection

Data collection was carried out using a structured case record form (CRF) along with the Morisky Medication Adherence Scale (MMAS-8). The CRF was designed to capture comprehensive patient-related information, including socio-demographic parameters (age, sex, educational status, and occupation), lifestyle attributes (smoking status, alcohol use, and physical activity), and clinical data such as duration of diabetes, complications, and the ongoing treatment regimen.

Assessment of Medication Adherence

Medication adherence was evaluated using the MMAS-8, a validated 8-item questionnaire specifically designed to measure self-reported adherence behaviors among patients with chronic diseases. Each item addressed a distinct aspect of adherence behaviour, including forgetfulness, intentional discontinuation, regimen inconvenience, and psychological attitudes towards medication. Responses were scored dichotomously, where each non-adherent behaviour was scored as "1" and adherent behavior as "0." The cumulative score ranged from 0 to 8, with higher scores indicating better

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2019 1. Low- and middle-income countries bear a large share of this burden. India, for example, has one of the highest diabetes populations in the world, with an estimated 77 million cases in 2019 projected to climb to 134 million by 2025 2. This burgeoning epidemic has earned India the moniker of the "diabetic capital of the world," and it poses enormous challenges for the healthcare system 3. Effective management of type 2 diabetes mellitus (T2DM) relies on both lifestyle modifications and pharmacotherapy. Medication adherence, defined as the extent to which patients take medications as prescribed, is crucial for achieving optimal glycemic control and preventing complications. Despite its importance, medication adherence in T2DM is often suboptimal. Reported adherence rates vary widely (approximately 30% to 80% in different settings), with many patients failing to consistently take their antidiabetic medications. Non-adherence contributes to poor glycemic control, an increased risk of microvascular and macrovascular complications, and higher healthcare costs. Indeed, the World Health Organization (WHO) has highlighted that improving adherence may have a greater impact on health outcomes than any new medical advances in diabetes therapy. Multiple factors influence whether patients adhere to treatment, including patientrelated factors (e.g., knowledge, motivation, and psychosocial support), therapy-related factors (such as the complexity of the regimen, side effects, and cost), and healthcare system factors. Prior studies in various regions have identified age, educational level, socioeconomic status, disease knowledge, comorbidities, and polypharmacy (multiple medications) as potential determinants of adherence. However, these factors can vary across different populations and contexts.

Treatment adherence in T2DM remains a major challenge in clinical practice, and there is a need for more region-specific data to inform targeted interventions. In this study, we aimed to assess the level of medication adherence among patients with type 2 diabetes in a tertiary care hospital and to identify the key factors associated with their adherence. This investigation will help to better understand the extent of the adherence problem in this setting and provide insights for designing strategies to improve adherence and, ultimately, diabetes outcomes.

Materials and Methods Study Design and Setting

This was a cross-sectional observational study conducted in the Department of Pharmacology in collaboration with the Department of Endocrinology at Maharaja Krushna Chandra Gajapati Medical College and Hospital, Berhampur, Odisha. The study was conducted over three months from August 2023 to October 2023.



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adherence. For analytical purposes, patients were categorized into two groups based on their MMAS-8 scores: those scoring less than 6 were considered non-adherent (low adherence), while those scoring 6 or more were classified as adherent (high adherence). This dichotomization facilitated the comparative analysis of adherence-associated factors.

Statistical Analysis

All collected data were entered into a Microsoft Excel worksheet and subjected to statistical analysis using IBM SPSS Statistics for Windows, Version 22.0. Continuous variables, such as patient age, were expressed as mean values with corresponding standard deviations. Categorical variables, including gender distribution, treatment regimens, and adherence categories, were represented using frequencies and percentages. To determine the association between categorical variables and adherence status, the chi-square test was employed. Statistical significance was defined as a p-value of less than 0.05 for all inferential analyses.

Ethical consideration

Before the initiation of the study, ethical clearance was obtained from the Institutional Ethics Committee, and written informed consent was obtained from all participants after fully informing them about the nature and purpose of the study.

Results

A total of 96 adult patients with a known diagnosis of T2DM were initially screened for eligibility during the study period. Of these, 86 patients fulfilled the inclusion criteria and were confirmed eligible. Among them, 5 patients declined participation due to personal reasons, resulting in 81 patients being enrolled. During the course of the study, 5 participants were further excluded: three had incomplete data records, and two withdrew consent after initial enrollment. Consequently, 81 participants were included in the final analysis, thereby meeting the calculated sample size requirement.

This sequential recruitment process minimized bias by ensuring consecutive eligible patients were enrolled. The flow of participants at each stage is depicted in Figure 1 (Participant Flow Diagram).

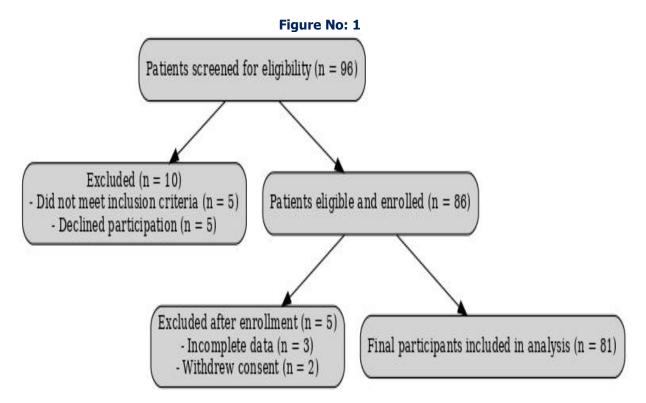


Table No. 1: Demographic Data of Participants

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Demographic characteristics		Frequency (%)	Mean± S.D
Age in Years	< 60	54 (66.7)	51.07±11.08
	≥ 60	27 (33.3)	
Gender	Male	57(70.4)	
	Female	24(29.6)	
Occupation	Labour	24 (29.6)	
	Business	25(30.9)	
	Housewife	23(28.4)	
	Teacher	3(3.7)	
	Dependent	6(7.4)	
Education	Illiterate	41(50.6)	
	Literate	40 (49.4)	
Lifestyle	Working	48 (59.3)	
	Sedentary	33 (40.7)	
Exercise	Yes	51(63.7)	
	No	30 (37.0)	
Addiction	Yes	55(67.9)	
	No	26(32.1)	
Drug therapy	≤2 drugs	50(61.8)	
	>2 drugs	31(38.2)	
Medication Adherence	Highly Adherent	24(29.6)	
	Low Adherent	57(70.4)	

Table 1 showed that more participants belonged to the age group of less than 60 (66.7%). The mean age of the study participants was 51.07 ± 11.08 years. A larger

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number of participants were male (70.4%), belonged to the working lifestyle group (59.3%), illiterate (50.6%), and associated with addiction (67.9%), respectively.

Table No. 2: The Association between patient-adherence classes and the demographic and clinical variables of diabetic patients. (n=81)

<u> </u>		Non-adherence	Adherence	P value
Age group	<60	33	21	0.008**
	≥60yrs	24	3	
Gender	Male	39	18	0.606
	Female	18	6	
Educational Status	Illiterate	33	7	0.02**
	Literate	24	17	
Lifestyle	Working	29	19	0.02**
	Sedentary	28	05	
Exercise	Yes	32	19	0.04**
	No	25	5	
Drug therapy	≤2 drugs	29	21	0.002**
	>2 drugs	28	3	
Duration of therapy	Yes	16	10	0.299
	No	41	14	



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Table No. 2 depicted that a statistically significant association was observed between age and adherence (p = 0.008), with patients aged \geq 60 years demonstrating lower adherence compared to those aged <60 years. Educational status also showed a significant relationship with adherence (p = 0.02), as literate individuals were more likely to be adherent to their treatment regimen than illiterate patients. Lifestyle characteristics revealed that working individuals had significantly better adherence compared to those with a sedentary lifestyle (p = 0.02). Similarly, patients who engaged in regular exercise showed higher adherence (p = 0.04) than those who did not exercise. The drug therapy regimen was another significant factor; patients on two or fewer medications exhibited significantly better adherence compared to those on more than two medications (p = 0.002). In contrast, gender and duration of therapy did not show statistically significant associations with adherence status (p = 0.606 and p = 0.299, respectively).

Discussion

In this cross-sectional study of type 2 diabetes patients at a tertiary care hospital, researchers found that treatment adherence was suboptimal, with only about 30% of patients classified as adherent to their medication regimen. In other words, approximately 70% of patients were non-adherent, which is alarming as it exposes a large majority to the risk of poor glycemic control and diabetes-related complications. The findings of this study reinforce a growing body of evidence from various regions indicating that medication non-adherence is a pervasive problem among T2DM patients.

A recent study in a similar tertiary-care setting in South Odisha reported that 46% of diabetic patients were adherent to medications. This adherence rate, while low, is somewhat higher than the 29.6% adherence observed in this study. The discrepancy could be due to differences in the patient population or methodology 5. Notably, both studies highlight that more than half of patients are not adequately adhering to their therapy, underscoring a consistent challenge. The present study's findings are closely aligned with those of a study from northern India, which found that only about 32% of T2DM outpatients took their medications as prescribed 6. Similarly, a hospital-based study in eastern India observed an adherence rate of just 34%. On the other hand, a study in a rural Karnataka population reported that roughly 51% of patients had good adherence (and 49% poor adherence) – a relatively better outcome, nonetheless still demonstrating that half of the participants were non-adherent 3. These variations in adherence rates (ranging from ~30% to 50% in different Indian settings) likely reflect differences in healthcare access, patient education, socio-cultural factors, and how adherence was measured. Nonetheless, the consistent

theme is that a large proportion of Indian T2DM patients do not adhere to medications adequately, which is in line with global observations of adherence problems in chronic diseases.

The Current study identified several factors associated with non-adherence that are also corroborated by other research. Older age was significantly linked to poorer adherence in our cohort. This trend has been noted in previous studies, which found that elderly patients were more likely to be non-adherent compared to younger patients 5. Advancing age might contribute to nonadherence due to forgetfulness, cognitive decline, complex medication regimens for multiple comorbidities, or lack of caregiver support. It is also possible that younger patients in our study, being relatively recently diagnosed or actively working, were more motivated to control their disease. In contrast, some studies have reported no age effect or even better adherence in older patients who may be more healthconscious; however, the bulk of evidence in diabetes suggests older patients often face adherence challenges. Our finding reinforces the need for special attention and tailored interventions (like pill organizers, reminders, or caregiver involvement) for older diabetic patients.

Educational status emerged as a significant determinant of adherence, with patients having higher levels of education being more adherent to their treatment regimen. This is intuitive, as education likely enhances health literacy and understanding of disease and treatment benefits. A study from North India similarly reported that patients' educational level had a significant association with adherence rates 6. In their study, literate patients were found to be more compliant, a finding that parallels our results. A study in rural Karnataka also noted that literacy status was a significant factor, with non-adherence more common in those with limited education 3. Education may influence one's ability to comprehend medical instructions, navigate the healthcare system, and prioritize long-term financial treatment. Our findings underscore the importance of patient education and counseling - simplifying medical information and ensuring that even patients with low literacy fully understand how and why to take their medications can potentially improve adherence.

Lifestyle factors were significantly associated with adherence in our analysis. Patients leading a sedentary lifestyle or not following the recommended diet/exercise were more likely to neglect their medications as well. This suggests that medication adherence is part of a broader spectrum of self-care behaviors. A study in Karnataka found that personal motivation and family support correlated with adherence to diabetes self-care (including medications), indicating that patients who are generally motivated to manage their diabetes (by exercising, eating healthy, etc.) also tend to be more



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adherent to pills. A study from Eastern India observed that patients who adhered to a diabetic diet plan had significantly better medication adherence, and those with unhealthy habits (like current alcohol use) had worse adherence. These findings align with our observation that poor lifestyle habits go hand-in-hand with poor medication adherence 4. It underlines that improving medication adherence may require a holistic approach – for example, structured diabetes education programs that address diet, exercise, and medication together, and involve family members to support a healthy lifestyle, could be beneficial. Additionally, addressing barriers to lifestyle change (such as a lack of time, cultural dietary practices, or limited access to exercise facilities) may also indirectly improve medication-taking behavior.

One notable factor affecting adherence in our study was polypharmacy, or the use of multiple medications. The study found that patients on more complex regimens (e.g., combining insulin with oral drugs, or taking multiple pills) had significantly lower adherence. This is a well-documented phenomenon: as the number of pills or dosing frequency increases, adherence tends to decrease due to forgetfulness, inconvenience, or fear of side effects 7. Additionally, a North India-based study reported that the quantity and type of anti-diabetic drugs were significantly related to adherence - patients on insulin or multiple oral agents were less adherent. In a longitudinal pharmacotherapy study, it was noted that T2DM patients in India often require an average of two anti-diabetic drugs per prescription to achieve control 7. While combination therapy is frequently necessary to manage diabetes (especially in long-standing cases or those with complications), our results highlight a critical trade-off: complex regimens may undermine adherence, thereby reducing the intended benefits of intensive therapy. This finding suggests that clinicians should strive to simplify treatment regimens whenever possible (for example, by using fixed-dose combination pills, once-daily formulations, or simplifying insulin schedules) and ensure that patients are thoroughly educated on how to manage multiple medications effectively. Additionally, the use of reminders or pill boxes can help patients cope with polypharmacy. In some cases, if non-adherence is suspected, it may even be prudent to prioritize a slightly less intensive but simpler regimen that the patient can adhere to, rather than a theoretically optimal regimen that the patient will not follow.

Interestingly, neither gender nor the presence of comorbidities showed significant associations with adherence in our study. Some other studies have found a significant association with gender, implying that one gender (in their case, possibly males) had better adherence. In this cohort, however, both men and women exhibited similarly poor adherence rates, suggesting that gender itself was not a determinant. This could be due to our sample characteristics or cultural context, where both males and females may face similar challenges in taking medications (though reasons might differ, such as men neglecting care due to work and women due to family responsibilities). Regarding co-morbid conditions, a study found that having any co-morbidity (like hypertension) increased the risk of poor adherence by three-fold, presumably because of pill burden or competing health priorities 4. Another study from South Odisha also identified comorbidity as a significant factor for non-adherence. In our study, while patients with comorbidities did have a higher proportion of nonadherence, the difference wasn't statistically significant - possibly due to our small sample or the fact that nearly all patients had at least one co-morbidity (hence limited contrast). Nonetheless, it is reasonable to be vigilant that patients juggling multiple chronic illnesses might struggle more with adherence, and they may need integrated management plans (e.g., synchronized medication timing or combined disease education sessions).

Generalisability

The findings of this study offer important insights into medication adherence patterns among patients with type 2 diabetes mellitus (T2DM) in a tertiary care hospital in South Odisha. However, due to the single-center design and limited sample size, the results may not be fully generalizable to the broader diabetic population across different geographic regions, rural settings, or private healthcare facilities in India. Variations in socioeconomic status, healthcare accessibility, and cultural beliefs can influence adherence behaviours differently across populations. Thus, while the study provides valuable region-specific data, multi-center studies with larger and more diverse populations are needed to enhance generalisability and guide national-level interventions.

Conclusion

This cross-sectional study, conducted at a tertiary care centre in South Odisha, revealed that medication adherence among patients with type 2 diabetes mellitus (T2DM) was suboptimal, with high adherence rates as measured by the MMAS-8 scale. A significant were categorized as non-adherent. highlighting a pressing concern in diabetes management. Several socio-demographic and clinical factors were significantly associated with adherence levels. Younger age, literacy, an active lifestyle, regular exercise, and simpler pharmacotherapy (using ≤2 drugs) were all positively associated with better adherence. Conversely, age, sedentary lifestyle, illiteracy, and polypharmacy were linked to poor adherence. However, neither gender nor duration of therapy was significantly



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related to adherence status. These findings underscore the multifactorial nature of non-adherence and suggest that targeted, patient-centered interventions—such as health literacy programs, lifestyle counselling, simplification of drug regimens, and adherence support tools—are urgently needed to improve treatment outcomes in T2DM. Tailoring strategies to address specific barriers within this population can play a crucial role in optimizing glycemic control and reducing the burden of diabetes-related complications.

Limitations

This study has several limitations that may impact the interpretation of its findings. The cross-sectional design limits the ability to establish causal relationships between medication adherence and associated factors, as it captures data at a single point in time. The relatively small sample size, drawn from a single tertiary care reduces the statistical power generalisability, particularly for subgroups such as elderly or female patients. The use of the self-reported MMAS-8 questionnaire to assess adherence introduces potential recall and social desirability biases, which may lead to an overestimation of adherence. Furthermore, the absence of objective biochemical measures, such as HbA1c, prevents correlation with actual glycemic control. Additionally, important confounding factors such as income, psychosocial support, beliefs about medication, and healthcare access were not assessed, which may have influenced adherence outcomes.

Recommendations

Based on the findings of this study, it is recommended that targeted interventions be implemented to improve medication adherence among patients with type 2 diabetes mellitus. Emphasis should be placed on patient education and counseling, particularly for older adults and individuals with low literacy, to enhance their understanding of the disease and the importance of adhering to a consistent medication regimen. Integrating structured lifestyle modification programs, including physical activity and dietary guidance, into routine diabetes care may reinforce self-care behaviours and promote better adherence. Efforts should also be made to pharmacotherapeutic regimens simplify appropriate. The use of fixed-dose combinations or once-daily formulations can help reduce pill burden and improve compliance, especially among patients on multiple medications. Additionally, incorporating reminder tools—such as mobile phone alerts, pillboxes, or caregiver support—can help mitigate forgetfulness and enhance daily adherence. Special attention should be given to high-risk groups identified in the study, such as the elderly, sedentary individuals, and those prescribed complex drug regimens, by

designing customized adherence support strategies. Finally, future research should aim to include larger and more diverse populations through multi-center, longitudinal studies, incorporating objective adherence measures such as HbA1c levels and prescription refill records. It is also essential to assess psychosocial, economic, and healthcare access-related variables to develop a more comprehensive and context-specific understanding of adherence behaviour.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this study.

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Data Availability

De-identified individual participant data, CRF template, and SPSS output files are available upon reasonable request to the corresponding author, subject to IEC approval.

Abbreviation Full Form

T2DM: Type 2 Diabetes Mellitus WHO: World Health Organization OPD: Outpatient Department CRF: Case Record Form

MMAS-8: Morisky Medication Adherence Scale - 8

Item

OR: Odds Ratio

CI: Confidence Interval

SPSS: Statistical Package for the Social Sciences

SD: Standard Deviation HbA1c: Glycated Hemoglobin

MKCG: Maharaja Krishna Chandra Gajapati (Medical

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Author Contributions

- Dr. Santosh Kumar Das: Conceptualization of the study, development of methodology, data collection, statistical analysis, drafting of the initial manuscript.
- **Dr. Jayanti Prava Behera**: Supervision, validation of methodology, and critical revision of the manuscript for intellectual content.
- Dr. Suvendu Kumar Panda: Study design, oversight of data analysis, interpretation of results, manuscript writing, and corresponding author responsibilities.
- **Dr. Srikanta Panigrahy**: Assistance in data collection, literature review, preparation of tables and figures, and manuscript editing.

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