International Journal of Applied Pharmaceutics

ISSN- 0975-7058 Vol 17, Special Issue 2, 2025

Original Article

DETERMINATION OF FACTORS AFFECTING MEDICATION ADHERENCE IN TYPE 2 DIABETES MELLITUS PATIENTS IN A TERTIARY HOSPITAL: CASE-CONTROL STUDY

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Received: 10 Mar 2025, Revised and Accepted: 14 May 2025

ABSTRACT

Objective: Several variables can impact medication adherence. Patients with type 2 diabetes mellitus (T2DM) still have low medication adherence, which increases their risk of hospitalization, uncontrolled blood sugar levels, and consequences from other illnesses. The study aimed to identify variables associated with medication adherence in T2DM outpatients to define a pharmacist intervention model or digital adherence technologies developed to improve medication adherence.

Methods: A case-control study was conducted on a sample of 100 respondents. A census was conducted on all outpatients of T2DM at the Tertiary Hospital in Central Java, Indonesia, from June 1st to July 31st 2024 to select cases and control groups after out and completing the questionnaire. The medication adherence questionnaire used in this study is a self-developed questionnaire by the researcher, which has been tested for validity (r>0.361) and reliability (0.737). Adherence was analyzed descriptively, where a score of 9 indicated adherence. Bivariable and multivariable logistic regression was used to evaluate adherence factors.

Results: The respondent's adherence to medication was 60% as measured by the Medication adherence questionnaire for T2DM. Occupation, health insurance, number of DM medications, duration of therapy, comorbidities, gender, age, and family support had no significant effect on patient adherence (p>0.05). Factor significantly associated with medication adherence were education level (OR = 2.513, p = 0.028).

Conclusion: Education can influence patient medication adherence. Pharmacists can actively contribute by providing education and counseling to improve patients' understanding of their disease and enhance medication adherence.

Keywords: Adherence, Diabetes mellitus, Indonesia, Socio-economic factors

DOI: https://dx.doi.org/10.22159/ijap.2025.v17s2.20 Journal homepage: https://innovareacademics.in/journals/index.php/ijap

INTRODUCTION

The International Diabetes Federation estimates that as many as 485 million people aged 20-79 y will suffer from diabetes mellitus in 2021. People with diabetes mellitus (DM) have a higher incidence of infectious and cardiovascular diseases if the glucose level is uncontrolled [1–4]. Medication adherence is critical for treatment efficacy because DM is a chronic condition requiring continuous management. Average patient compliance rates range from 34.6% to 80% in patients with chronic diseases [5, 6]. Various factors, including treatment adherence and medication choice, might influence the effectiveness of diabetes management [7–9]. Adherence involves not only assessing the patient's therapy but also implementing the recommendations of healthcare professionals, including nutritional, exercise, and lifestyle modifications [10–12].

Various factors, such as age, male gender, educational attainment, wealth, healthcare providers, the number of drugs prescribed, and costs, can influence the adherence of diabetes mellitus patients to their prescription regimens [13–15]. Comorbidity, family history of DM, and alcohol drinking habits can increase the odds ratio (OR) value of the possibility of poor adherence [16]. DM patients who have family support have a Morisky Medication Adherence Scale-8 (MMAS-8) score>6 and have reasonable glycemic control [17].

In a study conducted at Primary Health Centers in Saudi Arabia, 21.5% of patients had low adherence and were associated with gender and duration of therapy [15]. According to a different study that used a database of pharmacy claims, up to 69.1% of patients adhere, with patients who had recently had DM medication having a lower adherence rate (29.8%) [13]. According to a study conducted at Central Java Hospital, 37 (43.5%) respondents were adhere to their medication. The study also revealed a significant correlation between diabetic patients' adherence and the following factors: monthly income, medication, frequency of treatment, and blood glucose level [10]. The prior clearly indicates that diabetes mellitus patients exhibit inadequate treatment adherence.

Medication adherence contributes to an improved quality of life in type 2 diabetes mellitus patients [18]. Poor adherence can elevate the risk of adverse outcomes and undermine treatment efficacy. Patients with diabetes exhibit a complex and multidimensional degree of adherence. This study is needed to determine factors affecting adherence to defined policies and appropriate strategies. By knowing the factors affecting adherence, it is hoped that a pharmacist intervention model or digital adherence technologies can be developed to improve medication adherence. Thus, this study aims to assess the determinants of adherence to antidiabetic medication among T2DM patients.

MATERIALS AND METHODS

Research design

This study was conducted at the Tertiary Hospital in Central Java, Indonesia, using an analytical observational study with a case-control design. Patients were interviewed to obtain information about their sociodemographic, adherence, and other relevant study data. The ethics team approved this research with number 707/V/HREC/2024 from the Health Research Ethics Commission of Dr. Moewardi Surakarta Regional General Hospital, Indonesia.

Patient sociodemographic and medication adherence data were gathered through patient interviews and self-administered questionnaires. The independent variables in this study are factors related to medication adherence, which include gender, age, education, occupation, number of medications, duration of illness, comorbidities, health insurance, and family support.

Sample size and sampling method

The sample size was estimated using the Epitools Ausvet 2025. Since no analogous research had been undertaken, a value of 50% was used to estimate the proportion of the control group. The assumed odds ratio is 4, the confidence level is 95%, and the power is 0.8. The sample size per group is 36. Considering a 10% non-response rate, the final sample size required for the study is 40 for each group.

The institution-based census was conducted on outpatients with T2DM who fulfilled the criteria between June and July 2024. The inclusion criteria for both control and case groups comprised outpatients diagnosed with type 2 diabetes mellitus, aged over 20 y, and utilizing either single or combination antidiabetic medications for more than 3 mo. Respondents who met the inclusion criteria were then asked to complete the Medication adherence questionnaire for T2DM to determine the control and case groups (60 patients in the control group and 40 in the case group). The control group demonstrates treatment adherence (score 9) and the case group exhibits non-adherence to treatment (score 0-8).

Research instrument

In this study, we did not use a golden instrument such as MMAS-8 because the respondents had relatively heterogeneous backgrounds, and we did not have an MMAS-8 license. Therefore, we needed to develop our own adherence instrument and validate its content and instrument. The questionnaire developed by the researcher, a pharmacist, which was used to measure the level of patient adherence, consisted of 9 closed question items: favorable (items 1, 2, 6, 7) and unfavorable (items 3-5, 8-9). Questions in the questionnaire describe three dimensions, namely drug use (items number 1-5), counseling (items 6-7), and the dimension of drug availability (items 8-9). Scores are measured using the Guttman scale, which has a firm answer to a problem with "yes" or "no". The questionnaire used in this study can be seen in table 1. A score of 9 indicates a high level of adherence, while a score of 0-8 indicates low adherence.

Table 1: Medication adherence questionnaire for T2DM

S. No.	Statement	Scale	
		Yes	No
1	Taking medication during the last 1 w	1	0
2	Take medication according to the instructions	1	0
3	I'm too lazy to take my medicine	0	1
4	I forgot to take the medicine	0	1
5	I did not take medication if my blood sugar was normal	0	1
6	I consulted a doctor if I wanted to stop taking the medication.	1	0
7	I visit the doctor regularly according to the schedule.	1	0
8	I ran out of medication before my scheduled visit to the doctor	0	1
9	I don't take any medication with me when I travel.	0	1
	Total score		

Score category: 9High adherence, 0-8Low adherence

Content validity coefficient

Content validity assessment is based on Aiken's formula (1985) involving one expert lecturer at the Faculty of Pharmacy, Universitas Muhammadiyah Surakarta, one internal medicine specialist, and two clinical pharmacists at a tertiary hospital in Surakarta. The measurement scale is ordinal: 1 = not relevant, 2 = somewhat relevant, 3 = quite relevant and 4 = very relevant. The Aiken's coefficient value (V) ranges from 0-1. A coefficient of 0.857 can be considered to have adequate content validity [19].

Aiken's formula: $V = \sum s/[n(C-1)]$

$S = r - lo$

Lo = lower value (1)

C = higher value (4)

R = value from expert

Table 2: Content validity results of the medication adherence questionnaire for T2DM

S. No.	Dimension	Statement	Value from expert				∑ s	V-value	Criteria
			A	B	C	D			
1	Drug use	P1	4	4	4	4	12	1	Valid
2		P2	4	4	4	4	12	1	Valid
3		P3	4	4	4	4	12	1	Valid
4		P4	4	4	4	4	12	1	Valid
5		P5	4	4	4	4	12	1	Valid
6	Counseling	P6	4	4	4	4	12	1	Valid
7		P7	4	4	4	4	12	1	Valid
8	Drug availability	P8	4	4	4	4	12	1	Valid
9		P9	3	4	4	4	11	0.92	Valid

Validity and reliability test

The questionnaire has undergone validity and reliability testing with 30 research samples. The validity test used the Corrected Correlation technique with the statistical package for social sciences (SPSS). The validity test results for the Adherence Questionnaire, encompassing nine statements, yielded values ranging from r = 0.377 to 0.708. All items in the questionnaire were evaluated against the 5% significance level threshold (r>0.361). The questionnaire reliability test yielded a Cronbach's alpha value of 0.737, falling within the $0.7 \leq \alpha \leq 0.9$ range. The validity and reliability test results indicate that the adherence questionnaire is valid and suitable for measuring outpatient DM adherence at Tertiary Hospital in Central Java, Indonesia.

Data analysis

Data analysis is performed using SPSS version 25. Univariate analysis was employed to examine the characteristics of respondents. Bivariate analysis employing the chi-square test was

conducted to assess the relationship between factors affecting medication adherence and behavioral adherence. Variables with a p-value<0.25 in the bivariable logistic regression analysis were entered into the multivariable logistic regression. A p-value<0.05 is deemed statistically significant. The Odds Ratio (OR) is employed to quantify the association between variables.

RESULTS AND DISCUSSION

Respondent characteristics

This study presents the characteristics of the respondents in table 3. Among patients with diabetes mellitus, the majority are female, comprising 52 patients (52%). The age distribution indicates that 51 patients (51%) are under 60, with a mean age of 60±9.5 y. This study suggests that 56 patients (56%) have low educational attainment, which is defined as not being in school or having completed elementary or junior high. Additionally, 55 patients (55%) are employed. Patients received a more significant proportion of combination antidiabetic drug therapy, with 63 (63%) utilizing combination therapy compared to 37 (37%) on single treatment, over a duration exceeding one year for 75 (75%) of the patients. A total of 69 (69%) patients do not have comorbidities, and 28 (28%) patients have family support in taking medication, while 96 (96%) patients utilize health insurance. Each respondent characteristic has a p-value>0.5, so there is no significant difference between the control group and the case group.

Table 3: Characteristics of outpatient type 2 diabetes mellitus at tertiary hospital for the period of June-July 2024

Variables	Category	Controls (n%)	Cases (n%)	Total (n%)	1p-value
Gender	Male	26 (43.3)	22 (55.0)	48 (48.0)	0.253
	Female	34 (56.7)	18 (45.0)	52 (52.0)	
Age (year)	20-60	28 (46.7)	23 (57.5)	51 (51.0)	0.288
	>60	32 (53.3)	17 (42.5)	49 (49.0)	
Mean±SD				60±9.5	
Patient education	High education	21 (35.0)	23 (57.5)	44 (44.0)	0.026
	Low education	39 (65.0)	17 (42.5)	56 (56.0)	
Occupation	Not working	28 (46.7)	17 (42.5)	45 (45)	0.682
	Working	32 (53.3)	23 (57.5)	55 (55)	
Number of DM medication	Monotherapy	24 (40.0)	13 (32.5)	37 (37.0)	0.447
	Combination (>1)	36 (60.0)	27 (67.5)	63 (63.0)	
Duration of therapy	<1 y	18 (30)	7 (17.5)	25 (25)	0.157
	1-3 y	42 (70)	33 (82.5)	75 (75)	
Comorbidities	No	42 (70)	27 (67.5)	69 (69)	0.791
	Yes	18 (30)	13 (32.5)	31 (31)	
Family support	Yes	18 (30)	10 (25)	28 (28)	0.585
	No	42 (70)	30 (75)	72 (72)	
Health Insurance	Yes	57 (95)	39 (97.5)	96 (96)	0.532
	None	3 (5)	1 (2.5)	4 (4)	

Note: DM = Diabetes Mellitus, 1 Chi-square test, 95% confidence level (significance p-value<0.05).

Table 4: Factors affecting medication adherence in type 2 diabetes mellitus outpatients in Tertiary Hospital for the period of June-July 2024

Dimension affecting adherence (WHO)	Indicator	Controls (n%)	Cases (n%)	[1]OR (95% CI)	p-value
Social and Economic Factors	Patient Education			2.513 (1.105, 5.712)	0.028*
	High education	21 (35.0)	23 (57.5)		
	Low education	39 (65.0)	17 (42.5)		
	Occupation			0.845 (0.377, 1.892)	0.682
	Not working	28 (46.7)	17 (42.5)		
	Working	32 (53.3)	23 (57.5)		
Factors related to the health system	Health Insurance			2.053 (0.206, 20.464)	0.540
	Yes	57 (95)	39 (97.5)		
	None	3 (5)	1 (2.5)		
Factors related to patient therapy	Number of DM Medication				
	Monotherapy	24 (40.0)	13 (32.5)	1.385 (0.598, 3.205)	0.447
	Combination (>1)	36 (60.0)	27 (67.5)		
Factors related to the patient's diseases	Duration			2.020 (0.755, 5.410)	0.162*
	<1 y	18 (30)	7 (17.5)		
	1-3 y	42 (70)	33 (82.5)		
	Comorbidities			0.890 (0.376, 2.107)	0.791
	No	42 (70)	27 (67.5)		
	Yes	18 (30)	13 (32.5)		
Patient-related factors	Gender			1.598 (0.714, 3.577)	0.254
	Male	26 (43.3)	22 (55.0)		
	Female	34 (56.7)	18 (45.0)		
	Age			1.546 (0.690, 3.463)	0.289
	20-60 y	28 (46.7)	23 (57.5)		
	>60 y	32 (53.3)	17 (42.5)		
	Family support			0.778 (0.315, 1.921)	0.586
	Yes	18 (30)	10 (25)		
	No	42 (70)	30 (75)		

1 Chi-square test, 95% confidence level (significance p-value<0.05). *Eligible into the multivariable logistic regression, OR = Odds Ratio, DM = Diabetes Mellitus

Factors affecting medication adherence

The findings revealed that education level significantly influence patient adherence. Respondents with higher education were 2.5-fold more likely to adhere to taking their medication (OR = 2.513, p = 0.028). Patients who use health insurance was 2-fold more adhere to their medication than those who do not use insurance, but this result was not have a significant effect (OR = 2.053, p = 0.540). The factors related to the patient's disease studied were the duration of type 2 DM therapy and comorbidities. Patients with a duration of therapy of less than 1 y showed a 2-fold increased likelihood of treatment adherence compared to those with a more than one year of treatment, but it has no significant effect (OR = 2.020, p = 0.162) (table 4). After conducting a multivariate test, it was found that the factor that most influenced patient compliance was the level of education (table 5).

Table 5: Multivariate analysis factors affecting medication adherence in type 2 diabetes mellitus outpatients in Tertiary Hospital for the period of June-July 2024

Variables	Bivariat		Multivariate	
	OR (95%CI)	p-value	OR (95% CI)	p-value
Patient education	2.513 (1.105, 5.712)	0.028	2.426 (1.060, 5.554)	0.036*
Occupation	0.845 (0.377, 1.892)	0.682		
Health Insurance	2.053 (0.206, 20.464)	0.540		
Number of DM Medication	1.385 (0.598, 3.205)	0.447		
Duration	2.020 (0.755, 5.410)	0.162	1.889 (0.691, 5.167)	0.215
Comorbidities	0.890 (0.376, 2.107)	0.791		
Gender	1.598 (0.714, 3.577)	0.254		
Age	1.546 (0.690, 3.463)	0.289		
Family support	0.778 (0.315, 1.921)	0.586		

*Statistically significance<0.05

DISCUSSION

Medication adherence measurement can be done directly and indirectly. Direct adherence measurements include measuring drug levels in the blood and direct observation of patients' medication-taking behavior. This method is considered the most accurate but requires a lot of medical personnel and expensive costs. Indirect measurements can use pill counts, secondary database analysis, electronic monitoring, and questionnaires. The downside of this measurement is the risk of bias because patients are less likely to report non-adherence. However, indirect measurements can be shorter and cheaper. Questionnaires are the most frequently used measurements and have good reliability and validity. Some questionnaires that can be used to measure T2DM adherence levels are the Morisky Medication Adherence Scale (MMAS-8), the Morisky Green Levine Scale (MGLS), and the Medication Adherence Report Scale (MARS) [20, 21].

Multiple factors affecting medication adherence in diabetes mellitus patients in Indonesia. The factors encompass social and economic elements, health system and personnel-related issues, therapy-related considerations (quantity of medications, administration frequency, medication type), disease-related aspects (glucose levels, therapy duration), patient-related variables (gender, social support, knowledge level, treatment satisfaction), and disease management components (pharmacy counseling and education) [14, 22–24].

The social and economic dimensions that we have studied are education and occupation. The results showed that patients with high education were more likely to adhere to their medication. Consistent with prior studies on T2DM patients, education were found to be positively associated with the adherence behavior of patients [10, 25]. The employment impact is largely uncertain [26]. Poor medication adherence is associated with patient demographic factors (e. g., young age, low education level, and low income level). Most respondents in the cases group possess low educational attainment (56%) and employment status (57.5%). Intensive work activities may lead to patients neglecting follow-up appointments and failing to adhere to their prescription schedules [27, 28]. Education level does not affect medication adherence levels in patients with diabetes mellitus; however, a high level of education can increase awareness of glucose level management [8, 22]. Mobile medication reminder apps may be useful for patients who work full-time.

Based on WHO health system dimensions, the use of health insurance can affect patient adherence. This finding revealed that patients who use health insurance are more likely to adhere, but not statistically significant (OR = 2.053, p = 0.540). A systematic review states that payment of health costs has a negative impact on patient compliance [26]. Health insurance may not affect patient medication adherence; however, it may reduce the financial burden of expensive treatments, and patients become more informed about their treatment and the decision to undergo T2DM therapy [29, 30]

Factors affecting medication adherence related to patient therapy analyzed were the number of DM medications. The results of the analysis showed that the amount of DM medication was not correlated with the adherence of T2DM patients (OR = 1.385, p = 0.447). Contrary to various research indicated a correlation between the quantity of medicines and the degree of adherence (p<0.05) [10, 12, 13]. Patients with poorly regulated glucose levels are more likely to be prescribed a combination therapy for diabetes that includes a higher number of medications. However, the impact of the amount of medication and frequency of use is uncertain in all conditions [26]. Some studies state patients adhere better to simple treatment than complex therapy regimens [8, 31, 32]. A large number of drugs may make patients feel bored and forget to take their dose at certain times.

WHO dimensions affecting adherence related to the patient's diseases were the duration of therapy and comorbidities. This study showed that patients with a duration of treatment of less than 1 year were more likely to adhere to the medication therapy, but this did not have a significant effect (OR = 2.020, p = 0.162). In line with DM patients in India with a longer average duration of treatment, they had poor adherence but did not have a significant effect (p = 0.114) [16]. Patients with comorbidities are more prone to receiving a complex therapeutic regimen involving a greater quantity of medicines [33]. Patients have better adherence to simple treatment than complex therapy regimens [8, 31, 32]. The protracted period of therapy may lead patients to experience boredom from frequent visits to healthcare institutions, resulting in a tendency to neglect their scheduled appointments [34, 35].

The findings indicated that patient-related factors, including gender, age, and family support, were not associated with patient adherence (OR<2, p>0.05). This is different from the dimensions that influence compliance based on WHO. The findings correspond with earlier studies suggesting that gender, age, and familial support did not markedly affect the adherence of DM patients [16, 23]. A separate study indicated that gender influenced drug adherence (p = 0.003) [36]. The case group in this study comprised adults over 60 y (57.5%) and was predominantly male (55%). At the age of 60, Indonesians are typically still productive, with men often preoccupied with work, leading them to neglect medicine and

regular health check-ups. The family significantly contributes to the efficacy of therapy by offering motivation and support, hence enhancing patient adherence to treatment [17, 37–39].

The findings of this study significantly differ from those of certain prior investigations. Adherence is a multifaceted phenomenon. The WHO (2003) identifies five dimensions influencing adherence: socio-economic, system and health worker, therapy-related, condition-related, and patient-related factors. Numerous findings indicate that various factors can affect patient adherence, including alterations in environmental conditions, cultural influences, popular views toward sickness, and familial support [35, 40, 41]. Physicians typically recognize that adherence is a critical concern in the management of chronic patients, yet they face limitations in identifying and diagnosing inadequate drug adherence. Consequently, it is imperative to devise novel techniques to enhance adherence, which is achievable through the utilization of technologies and the engagement of healthcare providers. Digital adherence technologies such as mobile applications, cellphone short messaging services (SMS), electronic reminder devices (ERD), and ingestible sensors can be an alternative to improve medication adherence [42, 43]. Pharmacists can actively contribute by providing education and counseling to enhance patients' understanding of their condition and foster self-motivation to improve glycemic control and management.

This study has numerous limitations: 1) The sample size is insufficient, potentially compromising the conclusions; 2) No assessment of glycemic control (HbA1c) as an adherence validation measure; 3) Potential recall bias in self-reported adherence; 4) Factors that may influence adherence have not been thoroughly studied, and 5) Single-center design limits generalizability. A multicenter investigation with a bigger sample size and other adherence factors such as mean income and residence distribution may be required to identify the factors influencing patient adherence.

CONCLUSION

Factor significantly associated with medication adherence were education level (OR = 2.513, p = 0.028). Education can influence patient medication adherence. Pharmacists can actively contribute by providing education and counseling to improve patients' understanding of their disease and enhance medication adherence.

ACKNOWLEDGEMENT

The authors would like to acknowledge the financial support provided by Universitas Muhammadiyah Surakarta for the Tri Dharma Integration grant, reference number 265/FF/A.3-III/VI/2022.

AUTHORS CONTRIBUTIONS

ASW, DM, TY and AYN developed the research concept. ASW, TY, and AYN developed the research design; DM and SRO collected the research data and recapitulation and drafted the initial manuscript. DM, SRO, and RAMOS analyzed the data. All authors have read and approved the manuscript.

CONFLICT OF INTERESTS

All authors report no conflicts of interest

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