

Adherence to Anti-diabetic Medication and its Associated Factors among Diabetic Patients in an Urban Area of Kerala: A Cross-sectional Study

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ABSTRACT

Introduction: Treatment for diabetes depends not only on whether a patient takes their medication but also the timing, dosage, and persistence over years of treatment. Medication non adherence is common among diabetics and it is one of the leading public health challenges. It's a primary determinant for treatment failure in chronic diseases.

Aim: To determine the level of medication adherence and its associated factors among diabetic patients in an Urban Area of Palakkad, Kerala, India.

Materials and Methods: The present cross-sectional study was conducted among 404 diabetic patients in urban field practice area of Government Medical College Palakkad, Kerala, India during the period-20th July 2023 to 20th July 2024. The participants were selected using convenience sampling. The study variables included sociodemographic profile consisting of age, gender, religion, occupation, area of residence, socioeconomic status and diabetic profile such as age of onset of diabetes, duration of diabetes, family history of diabetes, medication-oral hypoglycaemic drugs/insulin/ both and content validated Morisky Green Levine scale was used to determine the adherence to diabetic medication. Data was entered in MS Excel

and analysed using Statistical software Statistical Package for Social Sciences (SPSS) version 25. The level of adherence was measured using descriptive statistics. Statistical association was found using Chi-square test and logistic regression, with a level of significance set at $p < 0.05$.

Results: A total of 404 individuals were enrolled in the study. Among the participants 336 (83%) were found to have moderate adherence and 68 (17%) had good adherence to anti-diabetic medication. About 145 (35.9%) had duration of disease less than five years. Among the study participants 360 (89.1%) were on hypoglycaemic drugs and 34 (8.4%) were on insulin. Association was found between adherence level and awareness regarding compliance ($p=0.003$), health insurance ($p=0.033$), perceived polypharmacy burden ($p=0.018$) and satisfaction with healthcare workers ($p=0.039$) on univariate analysis. Among these, only awareness regarding compliance was significantly associated with good adherence in multivariate analysis ($p=0.005$).

Conclusion: Adherence to anti-diabetic medication was moderate in most participants, and it was significantly influenced by medication awareness, perceived polypharmacy burden and access to health insurance.

Keywords: Morisky Green Levine scale, Oral hypoglycaemic agents, Patient compliance, Polypharmacy, Socioeconomic factors

INTRODUCTION

Diabetes is a global problem with devastating human, social and economic impact. Anti-diabetic medications play a major role in the glycaemic control of patients with diabetes. However, inadequate adherence compromises safety and treatment effectiveness, leading to increased mortality and morbidity [1]. Adherence remains a critical challenge globally and is influenced by barriers comprising patient, medication, and health system factors. Studies have indicated that non adherence was present among roughly half of patients with Type 2 diabetes, thereby reducing treatment efficacy and increasing morbidity and mortality risks [1,2]. Barriers affecting adherence often include medication side-effects, regimen complexity, cost, limited health literacy, forgetfulness, poor patient-provider communication, and psychosocial stressors such as burnout and financial constraints [3-5]. These challenges are made worse in areas where there is lack of resources that address them, where drug availability and access to diabetes education further impact adherence levels [6]. In the Indian context cultural and traditional beliefs, socioeconomic factors like low income, and health system-related factors like availability of medicines affect medication adherence among individuals diagnosed with diabetes. Additionally, lack of disease awareness and forgetfulness are

commonly reported, along with the influence of family and social support systems [7]. In a 2013 study in Kerala, 74% of study participants diagnosed with diabetes were found to have poor medication adherence [8]. Studies have been done in Kerala but community-based studies are less [9-11].

Hence, the present study was done to determine the adherence level and its associated factors among diabetic patients in an Urban Area of Palakkad district of Kerala, India thereby bridging gaps existing in regional adherence data and informing public health interventions.

MATERIALS AND METHODS

The present cross-sectional study was conducted among individuals diagnosed with diabetes in urban field practice area of Government Medical College Palakkad, Kerala, India. The study was carried out over a one year period from 20th July 2023 to 20th July 2024 after obtaining permission from Institutional Ethics Committee (IEC/ GMCPKD/09/2023/110/PKD). The study participants included individuals aged 18 years and above who had been diagnosed with type 2 diabetes mellitus for one year and above.

Sample size calculation: Sample size was calculated to be 311 using the formula for single proportion Z^2pq/d^2 considering the prevalence of diabetes in Kerala as 23.6% with relative precision

of 20% [9]. A 10% dropout adjustment was done to 311 to get the final sample size 346. A total of 404 eligible participants were included in the study.

The urban field practice area of Government Medical College Palakkad covers a population of 50000. Participants were selected using convenience sampling.

Inclusion and Exclusion criteria: Inclusion criteria were adults diagnosed with type 2 diabetes mellitus for one year and who provided written informed consent. Exclusion criteria were women diagnosed with gestational diabetes, newly diagnosed type 2 diabetes mellitus (less than 1 year) and those who did not give informed consent.

Study Procedure

The study variables included: (a) Sociodemographic profile consisting of age, gender, religion, occupation, education marital status, type of family, socioeconomic status were classified into Above Poverty Line (APL) and Below Poverty Line (BPL) [12]. Diabetic profile- age of onset of diabetes, duration of diabetes, type of drug- oral hypoglycaemic drugs/insulin/both. A content validated Morisky Green Levine scale was used to determine the adherence to diabetic medication [13]. It has four questions. The questions include forgetfulness to take medicine, carelessness about timing of medication and stopping medications when the person gets better or worse. Each question has a yes or no answer. One point is given for yes and 0 point is given for no. Then, scores are summed up. The maximum score is 4. If the score is 0 the adherence is good. If the score is 1 to 2 then adherence is moderate and score 3 or more suggests poor adherence and additional data on factors related to non adherence were added which included variables such as social causes, therapy-related, patient related factors and healthcare-related factors. Social causes included factors such as family worries, family support, economic dependence, cost of medicine and health insurance. Therapy-related factors include complexity of regimen, side-effects, high dose of drug and medication interfering with food pattern. Patient related factors included awareness of missing dose, forgetfulness, alternative medication without doctor's prescription, homemade medicine, polypharmacy, stigma and eye screening. Healthcare-related factors included time taken to consult doctor, satisfaction with healthcare workers and their healthcare advices about adherence.

STATISTICAL ANALYSIS

Data was entered in MS Excel and analysed using statistical software SPSS version 25. The level of adherence was measured using descriptive statistics. Statistical association was found using Chi-square test and logistic regression, with a level of significance set at $p < 0.05$

RESULTS

Among the 404 study participants 195 (48.3%) were more than 60 years of age, 233(57.7%) were females and 271 (67.1%) belonged to BPL. Most of the study participants were Unemployed 262 (64.9%) and 57 (14.1%) were unskilled, 159 (39.4%) are educated up to high school and 83 (20.5%) had education up to preprimary. Most participants 302 (74.8%) were married and 331 (81.9%) belonged to nuclear family, 145 (35.9%) had duration of disease less than five years. Among the study participants 360 (89.1%) were on hypoglycaemic drugs and 34 (8.4%) were on insulin [Table/Fig-1].

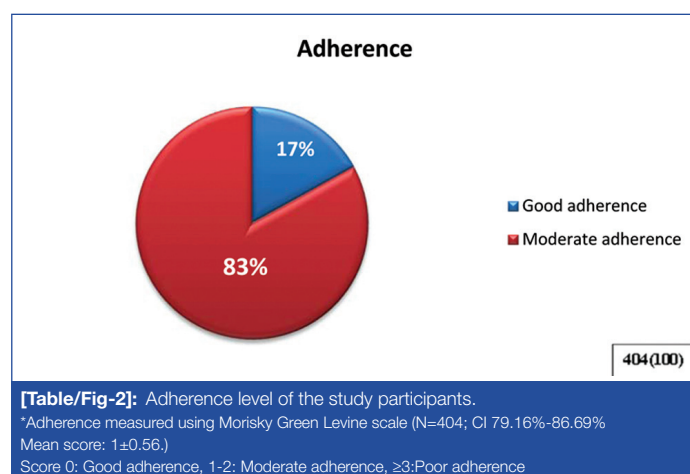
Adherence level of the study participants is shown in [Table/Fig-2]. A 17% demonstrated good adherence whereas 83% showed moderate adherence.

With respect to causes of non adherence about 164 (40.6%) had family stress, 343 (84.9%) had family support, 116 (28.7%) had economic dependence. Among 404 participants 138 (34.2%) felt the medicines were costly and 53% of the study participants didn't have health insurance. Therapy-related factors which included complex treatment regimen where only 49 (12.1%), side-effects

18 (4.5%) and lastly medication interference where about 224 (55.4%) felt medication was interfering with food pattern. Patient related factors included awareness about missing dose which was 306 (75.7%), forgetfulness 95 (23.5%), taking alternative medicine without doctor's prescription 10 (2.5%) [Table/Fig-3].

Sociodemographic profile	Variables	n (%)
Age (years)	30-40	11 (2.7)
	41-50	86 (21.3)
	51-60	112 (27.7)
	More than 60	195 (48.3)
Gender	Males	171 (42.3)
	Females	233 (57.7)
Religion	Hindu	236 (58.4)
	Muslim	156 (38.6)
	Christian	12 (3)
Socioeconomic status	Above poverty line	133 (32.9)
	Below poverty line	271 (67.1)
Occupation	Unemployed	262 (64.9)
	Unskilled	57 (14.1)
	Semiskilled	6 (1.5)
	Skilled	32 (7.9)
	Clerical/Shop Owner	16 (4)
	Professional	31 (7.7)
Education	Preprimary	83 (20.5)
	Primary	39 (9.7)
	Upper primary	69 (17.1)
	High school	159 (39.4)
	Higher secondary	54 (13.4)
Marital status	Married	302 (74.8)
	Single (divorced, widowed, single)	102 (25.2)
Type of family	Nuclear	331 (81.9)
	Joint	62 (15.3)
	Three generation	11 (2.7)
Age of onset (years)	Less than or equal to 40	81 (20)
	41-60	275 (68.1)
	More than or equal to 60	48 (11.9)
Duration of disease	Less than 5 years	145 (35.9)
	5 to 10 years	109 (27)
	Above 10 years	150 (37.1)
Type of drug taken	Hypoglycaemic drugs	360 (89.1)
	Insulin	34 (8.4)
	Insulin and hypoglycaemic drugs	10 (2.5)

[Table/Fig-1]: Sociodemographic profile.



Parameters	Present	Absent
Social causes		
Family Stress	164 (40.6)	240 (59.4)
Family support	343 (84.9)	61 (15.1)
Economic dependence	116 (28.7)	288 (71.3)
Costly medicine	138 (34.2)	266 (65.8)
Health insurance	190 (47)	214 (53)
Therapy-related		
Complex regimen	49 (12.1)	355 (87.9)
Side-effects	18 (4.5)	386 (95.5)
Medication interfering with food pattern	224 (55.4)	180 (44.6)
Patient-related factors		
Awareness of compliance	306 (75.7)	98 (24.3)
Forgetfulness	95 (23.5)	309 (76.5)
Alternative medicine without doctor's prescription	10 (2.5)	394 (97.5)
Homemade medicine	21 (5.2)	383 (94.8)
Perceived polypharmacy	36 (8.9)	368 (91.1)
Stigma	11 (2.7)	393 (97.3)
Eye screening done	281 (69.6)	123 (30.4)
Healthcare-related factors		
Long time to consulting doctor	110 (27.2)	294 (72.8)
Satisfaction with healthcare providers	298 (73.8)	106 (26.2)
Healthcare advices about adherence	382 (94.6)	22 (5.4)
[Table/Fig-3]: Factors related to non adherence.		
Values presented as n (%)		

A significant association was seen with health insurance, perceived polypharmacy burden, awareness about being compliant, and satisfaction with healthcare workers [Table/Fig-4].

Good adherence in those who did not perceive polypharmacy burden was 18.2% which showed significance in univariate analysis (p=0.018). Good adherence in those who had awareness regarding compliance was 19.9% also showed significant association (p=0.003) [Table/Fig-4].

Variables	Good adherence (68)	Moderate adherence (336)	p-value
Age (years)			
30-40	2 (18.2)	9 (81.8)	0.13
41-50	15 (17.4)	71 (82.6)	
51-60	26 (23.2)	86 (76.8)	
More than 60	25 (12.8)	170 (87.2)	
Gender			
Male	28 (16.4)	143 (83.6)	0.83
Female	40 (17.2)	193 (82.8)	
Religion			
Hindu	41 (17.4)	195 (82.6)	0.65
Muslim	24 (15.4)	132 (84.6)	
Christian	3 (25)	9 (75)	
Socioeconomic Status			
APL	27 (20.3)	106 (79.7)	0.204
BPL	41 (15.1)	230 (84.9)	
Occupation			
Unemployed	41 (15.6)	221 (84.4)	0.65
Unskilled	13 (22.8)	44 (77.2)	
Semiskilled	2 (33.3)	4 (66.7)	
Skilled	5 (15.6)	27 (84.4)	
Clerical/shop owner	3 (18.8)	13 (81)	
Professional	4 (12.9)	27 (87.1)	

Education			
Preprimary	16 (19.3)	67 (80.7)	0.39
Primary	7 (17.9)	32 (82.1)	
Upper primary	6 (8.7)	63 (91.3)	
High school	30 (18.9)	129 (81.1)	
Higher secondary	9 (16.7)	45 (83.3)	
Marital status			
Married	49 (16.2)	253 (83.8)	0.57
Single (divorced, widowed, single)	19 (18.6)	83 (81.4)	
Family type			
Nuclear	51 (15.4)	280 (84.6)	0.23
Joint	15 (24.2)	47 (75.8)	
Three generation	2 (18.2)	9 (81.8)	
Age of onset (years)			
Less than or equal to 40	10 (12.3)	71 (87.7)	0.409
41-60	48 (17.5)	227 (82.5)	
More than or equal to 60	10 (20.8)	38 (79.2)	
Duration of diabetes			
1- 5 years	27 (18.6)	118 (81.4)	0.059
5-10 years	24 (22.0)	85 (78.0)	
More than 10 years	17 (11.3)	133 (88.7)	
Type of drug taken			
Hypoglycaemic drugs	58 (16.1)	302 (83.9)	0.523
Insulin	8 (23.5)	26 (76.5)	
Insulin and hypoglycaemic drugs	2 (20)	8 (80)	
Family stress			
Present	33 (20.1)	131 (79.9)	0.175
Absent	35 (14.6)	205 (85.4)	
Family support			
Present	59 (17.2)	284 (82.8)	0.638
Absent	9 (14.8)	52 (85.2)	
Economic dependence			
Present	21 (18.1)	95 (81.9)	0.665
Absent	47 (16.3)	241 (83.7)	
Cost of medicine			
Expensive	27 (19.6)	111 (80.4)	0.290
Not expensive	41 (15.4)	225 (84.6)	
Health insurance			
Present	40 (21.1)	150 (78.9)	0.033
Absent	28 (13.1)	186 (86.9)	
Complex regimen			
Present	10 (20.4)	39 (79.6)	0.475
Absent	58 (16.3)	297 (83.7)	
Side-effects			
Present	4 (22.2)	14 (77.8)	0.532
Absent	64 (16.6)	322 (83.4)	
Medication interfering with food pattern			
Present	37 (16.5)	187 (83.5)	0.851
Absent	31 (17.2)	149 (82.8)	
Awareness about being compliant			
Yes	61 (19.9)	245 (80.1)	0.003
No	7 (7.1)	91 (92.9)	

Forgetfulness			
Yes	21 (22.1)	74 (77.9)	0.116
no	47 (15.2)	262 (84.8)	
Alternate medication without doctor's prescription			
Present	2 (20)	8 (80)	0.786
Absent	66 (17)	328 (83)	
Homemade medicine			
Yes	4 (19)	17 (81)	0.780
No	64 (16.7)	319 (83.3)	
Perceived polypharmacy burden			
Yes	1 (2.8)	35 (97.2)	0.018
No	67 (18.2)	301 (81.8)	
Stigma			
Present	4 (36.4)	7 (63.6)	0.079
Absent	64 (16.3)	329 (83.7)	
Eye screening			
Done	50 (17.8)	231 (82.2)	0.435
Not done	18 (14.6)	105 (85.4)	
Long-time to consult doctor			
Present	21 (19)	89 (81)	0.457
Absent	47 (16)	247 (84)	
Satisfaction with healthcare workers			
Satisfied	57 (19.1)	241 (80.9)	0.039
Not satisfied	11 (10.4)	95 (89.6)	
Healthcare advice received about adherence			
Present	66 (17.3)	316 (82.7)	0.555
Absent	2 (9.1)	20 (90.9)	
[Table/Fig-4]: Associations between various factors and adherence level. Values presented as n (%)			

Variables with $p < 0.2$ in univariate analysis were included for multivariate logistic regression where level of significance was set at 0.05.

Association between not perceiving polypharmacy burden and good adherence was not statistically significant in multivariate analysis however, awareness regarding compliance was significantly associated with good adherence in multivariate analysis ($p = 0.005$) with participants showing 3.8 times higher odds of being adherent to anti-diabetic medication compared with that lacked awareness [Table/Fig-5].

Parameters	Adjusted Odd's ratio	95% Confidence Interval (CI)		Sig
Age (years)				
30-40	1			0.438
41-50	0.723	0.102	5.101	0.745
51-60	1.031	0.149	7.106	0.976
More than 60	0.581	0.083	4.076	0.585
Family stress				
Yes	0.972	0.526	1.795	0.927
No	1			
Duration of diabetes				
1- 5 years	1			0.156
5-10 years	1.208	0.607	2.407	0.591
More than 10 years	0.579	0.267	1.253	0.165
Health insurance				
Yes	1			
No	1.625	0.903	2.922	0.105
Perceived polypharmacy burden				

Yes	0.835	0.346	2.014	0.688
No	1			
Awareness about compliance				
Yes	3.827	1.494	9.804	0.005
No	1			
Forgetfulness				
Yes	1.126	0.577	2.199	0.728
No	1			
Stigma				
Yes	4.029	0.946	17.169	0.060
No	1			
Satisfied with healthcare workers				
Yes	2.205	0.975	4.987	0.058
No	1			

[Table/Fig-5]: Multivariate logistic regression analysis of factors of associated with good adherence to anti-diabetic medication.

DISCUSSION

The present study aimed to assess the adherence and its barriers among individuals with diabetes mellitus in urban field practice area of the study Institute. The results of the study align and differ from the previous literature and the results must be interpreted with the socioeconomic background of Kerala where the state is currently having increasing burden of non communicable diseases due to rapid modernisation, consumer behaviour and high flow of funds from abroad [14]. The present study showed only 17% of the study participants were adherent and 83% were moderately adherent to diabetic medication, which was similar to study done by Sankar UV et al., where poor adherence was 74% [8]. When compared with a study done by Olickal JJ et al., among diabetic individuals in Pudukkottai using Morisky Green Levine Scale showed about 60.5% had good adherence and 39.5% had poor adherence which differed from the present study [15] Whereas a study done by Gaur R et al., using the same scale among 126 diabetic individuals showed about 57.14% were adherent and 42.86% were non adherent [16]. A good adherence of 60.9% was reported from a study done by Aravindakshan R et al., from a community based study in an urban area of southern Kerala [11]. Another community based study done by Usha Rani SP et al., among urban and rural population showed about 62% of the participants were adherent and 38% were non-adherent [17]. Similarly, study done by Venkatesan M et al., in Tamil Nadu showed about 45.5% of the study population had good adherence to diabetic medication [18] whereas a study done in an urban area of Karnataka by Nair RK et al., reported good adherence of 58.6% and poor adherence of 35.45% [19]. A study from a tertiary care hospital in New Delhi reported that 32.5% were found to have high adherence, while 34.5% and 33% had moderate and low adherence, respectively [20]. When compared with an international study done among diabetic individuals using the Morisky Green Levine scale showed 35.5% good adherence, 42.9% moderate adherence and 21.4% low adherence [21]. In a meta-analysis done by Basu S et al., reported prevalence of non adherence ranged widely from 11% to 68% which was due to substantial heterogeneity in adherence measured and study population [22]. Therefore, the variation in adherence with this study is likely explained. With respect to the factors affecting adherence the finding showed perceived polypharmacy, health insurance, awareness about compliance, satisfaction with healthcare workers contributed to moderate adherence. Certain findings aligned with study done by Venkatesan M et al., where perceived lack of doctor patient relationship (Odd's Ratio (OR)=3.3, CI=1.3-8.3) and lack of awareness (OR=1.9, CI=1.2-3.08) was one the reason attributed to poor adherence [18]. Similarly perceived polypharmacy was also reported by

Usha Rani SP et al., ($p=0.001$) and Kumar N et al., ($p=0.013$) as significant factor for non adherence [17,23]. In this study there was no significant finding where cost of medication and family support acted as barrier to adherence to diabetic medication however in study done by Sankar UV et al., without family support, chances of non adherence were 3.2 times higher [8]. Similar finding was also reported by Kumar H et al., ($p<0.001$), Angadi N et al., ($p=0.002$) [24,25]. The findings of this study also differed from that of Prasad M et al., where family support was associated with adherence ($p<0.001$) OR 3.549 [26]. Study done by Swain SP et al., reported about 30% of the diabetic individuals were adherent and suggested some predictors such as perceived polypharmacy, high cost of medicine as a constraint affecting good adherence to prescribed medicine [27]. Another study done by Govindani R et al., identified cost of medicine as a cause of non adherence among study participants. The study also found significant association ($p<0.0001$) between socioeconomic status and adherence [28]. Similarly, in a qualitative study done by Lalan RH et al., among diabetic individuals showed cost of medicine was a factor for non adherence where study highlights financial constraints often force patients to sacrifice their own health in favour of immediate family needs [29]. Study done by Medi RK et al., among 140 participants showed the reason for missing the dose was due to lack of finance 55.84% of participants [30]. Likewise, study done by Gupta R et al., also showed medicine was not affordable to 18.6% of participants [31], whereas Kumar H et al., reported no significant association ($p=0.018$) between cost and adherence which was also found in this study [24]. This study showed 55.4% had their Medication interfering with food pattern whereas study done by Dorvlo GGK et al., showed specific dietary choices such as high fibre food ($p=0.03$) and intake of processed and refined carbohydrate ($p=0.049$) were associated with poor adherence which indicated there is a relation between food intake and medication adherence [32]. With respect to side-effects this study showed no significant findings was found affecting adherence which was in contrast to a study done by Shukla J et al., where side-effects were significantly associated with adherence ($p<0.001$) [33]. With respect to duration of diabetes no significant association was found with adherence which is in contrast to another study done by Kottayi RT et al., where duration of diabetes is associated ($p=0.043$) with good adherence [34]. Similarly Acharya AS et al., also found duration of diabetes was associated ($p=0.002$) with adherence [20]. In the present study, 19.9% of adherent participants knew the importance of being compliant and was found as a predictor for adherence where they were 3.8 times more chance of being compliant. Whereas a study done by Venkatesan M et al., found the odds of low adherence for treatment among study participants who perceived lack of knowledge about diabetes increased by 1.9 times ($CI=1.2-3.1$) [18]. International studies done by Parajuli A et al., and has showed there was no association ($p=0.082$) between knowledge of diabetes and adherence level and Nurumal MS et al., reported Knowledge status of diabetes does not guarantee medication adherence [35,36]. In the present univariate analysis, a significant association was found between possession of health insurance and adherence this contrasts with finding of Mishra A et al., where health insurance has no association with adherence and social insurance showed a positive associated [37].

Limitation(s)

The present study has certain limitations. Causality between variables could not be established since this was a cross-sectional study. Convenience sampling was used and single area was selected and hence finding cannot be generalised. This study assessed the socioeconomic variables and psychological barriers but not clinical profiles such as HbA1c level, co morbidities and duration of treatment. Medication adherence was measured using self-reported questionnaire (MGL scale).

CONCLUSION(S)

Only 17% had good adherence to diabetic treatment. Diabetes management cannot be improved by distributing drugs alone. Simplified treatment regimens will help to overcome psychological barriers to adherence and it requires counselling on why and how to stay compliant.

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