

Interplay between Oral Hypoglycemic Medication Adherence and Quality of Life among Elderly Type 2 Diabetes Mellitus Patients

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ABSTRACT

Background: Adherence to medications is an important factor that contributes to therapeutic success. With the current increase in the elderly population, information relating to adherence to treatment and quality of life (QoL) of diabetic elderly patients will help the healthcare provider to improve their treatment. Thus, this study aims to determine the factors affecting adherence to medications and the consequence of non adherence to QoL.

Materials and Methods: This was a cross-sectional study using validated Morisky Medication Adherence Scale (MMAS) Questionnaire. This study was conducted to assess the level of adherence on oral hypoglycemic medications (OHM) and quality of life of the Type 2 diabetes mellitus (T2DM) elderly patients in an urban health centre in Malaysia. A retrospective medication record review was also conducted to collect and confirm data on patients' demographics, diagnosis, treatments, and outcomes.

Results: One hundred and seventy nine patients were recruited in this study. Median adherence score was 7.75 (IQR 6.50- 8.00). Good adherer was observed in 48.00% of the participants.

A Chi-square test indicated significant correlation between adherence and HbA1c ($p= 0.010$). The mean elderly diabetes mellitus Problem Areas in Diabetes (PAID) score was $6.30 \pm SD 8.50$. A significant inversed association was observed between PAID score and the level of adherence ($r = - 0.175$, $p < 0.05$). A highly significant difference in the low adherence group ($p = 0.002$). PAID score significantly correlated with age (years), female gender and HbA1c ($p < 0.05$). A negative association between HbA1c levels and adherence was identified where a 1% increase in HbA1c was associated with a 30% decrease in the likelihood of being adherent.

Conclusion: A medication adherence rate of 48% was obtained among elderly T2DM patients treated in the primary care clinic. This study showed that HbA1c is a relevant tool to assess patient glycemic control and adherence. Sociodemographic characteristics were not statistically significantly associated with adherence. We reported a negative correlation between adherence and T2DM related emotional distress. The identified factors that relieve emotional distress of the elderly T2DM patients are similar with the western countries.

Keywords: HbA1c, Malaysia, Morisky medication adherence scale, PAID score and public health care

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of most known chronic diseases in almost all countries, and continues to rise in numbers and significance, as change in lifestyle leads to lesser physical activity, and grow into obesity. With the existing and future burden of T2DM it is important to assign community and health funds, and to give emphasis to the role of lifestyle, and promote measures to counteract the increasing prevalence [1]. It is estimated the prevalence of adults with T2DM worldwide is 4.0% (135 million) and by 2025 this figure is expected to increase to 5.4% (300 million). The increase in the developing countries is 170%, whereby 42% increase in the developed countries [1]. By 2025, countries such India, China, and the United States will be the countries with the largest number of people with T2DM. The majority of people with T2DM in developing countries are in the age range of 45-64 y; meanwhile the majority of people with T2DM in the developed countries are aged >65 y. There are more women than men with T2DM particularly in developed countries. T2DM will be increasingly concentrated in urban areas in the future [2].

Patient non-compliance has often been associated with both medical regimens and self-care management practices because of the complexity of the regime [3,4]. The literature on clinical studies show a growing number of older adults having difficulty living and managing diabetes mellitus [5]. A retrospective study concluded that the adherence rate to oral antidiabetic agents ranged from 36 to

93% [6]. Poor glycemic control increased risk of developing chronic complications as well as increased hospitalization and mortality resulted from non adherence to medications among diabetic patients. Similarly, quality of life, side effects and complexity of medications, health care system issues; demographic, behavioral, treatment, and clinical variables, are among the numerous factors that affect patient adherence to prescribed therapies [7]. It is assumed that through individualized, often complex medical regime, individuals will achieve and maintain optimum glycemic control.

The objectives of this study were to assess the level of OHM adherence, the factors associated with adherence and the quality of life among elderly T2DM patients. Rather than simply focusing on the determinants of adherence, Problem Areas in Diabetes (PAID) scale questionnaire was used to gain a deeper understanding of the impact of diabetes mellitus on health and a holistic assessment of the overall health status.

MATERIALS AND METHODS

This cross-sectional survey was conducted at a Non Communicable Disease (NCD) Clinic and its outpatient pharmacy situated in Seremban City in the state of Negeri Sembilan in Malaysia from September 2012 to October 2012. The study population included patients aged 60 years and/or above, having T2DM since at least one year (being diagnosed in the clinic), and documentation of past HbA1c measurements with the details of OHM. Exclusion criteria

Variables	Mean±SD	Range
Age (years)	68.50±6.66	60.00 - 90.00
Duration of diabetes (years)	10.89±7.67	1.00 - 42.00
Number of medication	6.04±1.84	1.00 - 10.00
Body mass index	24.85±4.45	24.40-30.01
HbA1c (%)	7.45±1.85	4.80 - 13.60

[Table/Fig-1]: Characteristics of participants (N = 179)

Characteristics	Adherence level		p-value
	Low (N %) 93 (52.00%)	High (N %) 86 (48.00%)	
Gender			
Male	38 (40.90%)	39 (45.30%)	0.649
Female	55 (59.10%)	47 (54.70%)	
Ethnicity			
Malay	24 (25.80%)	16 (18.60%)	0.330
Chinese	30 (32.30%)	36 (41.90%)	
Indian	39 (41.90%)	34 (39.50%)	
Marital Status			
Single	31 (33.30%)	31 (36.00%)	0.823
Married	62 (66.70%)	55 (64.00%)	
Educational Level			
No formal education	19 (20.40%)	25 (29.10%)	0.407
Primary school	34 (36.60%)	28 (32.60%)	
Secondary school	40 (43.00%)	33 (38.40%)	
Last month income (USD)			
<300	69 (74.20%)	61 (70.90%)	0.748
>300	24 (25.80%)	25 (29.10%)	

[Table/Fig-2]: Distribution of demographic and clinical characteristics of the participants according to level of adherence

included patients who have cognitive, verbal problems or have difficulty to respond to the instruments of the study (blind, hearing problem, senility, psychiatric disorders), those who were unable to communicate in Malay or English and morbid patients unable to communicate with the researcher.

All eligible patients attending the clinic were approached and those who consented to the study were recruited by convenience sampling. A written consent form was obtained from every participant before providing the questionnaires. Patients' background data and the OHM history was screened prior to enrolment based on their medical records to confirm diagnosis. Patient demographic and medical data was collected via a designated form. The contents of the designated form were based on the information contains in the Ministry of Health diabetic card. The sample size used was estimated based on the number of elderly T2DM patients registered in the NCD clinic (N=695). The minimum effective sample size calculated for this study was 195 using the online sample size calculator Raosoft®, with a confidence interval of 90% and margin of error of 5% [8].

Research Instruments

Morisky Medication Adherence Scale (MMAS): The Morisky scale is a self-report adherence measure with four questions about common barriers to adherence. The Malay language version of validated Morisky Scale questionnaire was used. It has eight questions and is one of the most frequently used to assess patients' adherence to prescribed medicines in an outpatient setting. The self-reported measure of medication addresses the circumstances surrounding adherence behaviour such as; "do you sometimes have problems remembering to take your medication", "do you sometimes forget to take your medication," and problems with

Predictors variables	Odds ratio	(95% CI)	*p-value
Gender	1.017	(0.49-2.10)	0.964
Ethnicity	1.506	(0.64-3.54)	0.31
Marital status	0.961	(0.46-2.00)	0.92
Education	0.662	(0.26-1.50)	0.32
Income	1.491	(0.64-3.47)	0.35
HbA1c	0.767	(0.63-0.93)	*0.008
Age	1.018	(0.97-1.07)	0.48

[Table/Fig-3]: Logistic regression for factors predicting medication adherence

Characteristics	Adherence level Low (n %) 93 (52.00%)	Adherence level High (n %) 86 (48.00%)	p-value
Latest HbA1c (%)			
>6.5	68 (73.10%)	46 (53.50%)	*0.010
≤6.5	25 (26.90%)	40 (46.50%)	
BMI			
>24.9	63 (67.70%)	52 (60.50%)	0.310
24.9 or less	30 (32.30%)	34 (39.50%)	
Duration of diabetes (years)			
1' - 5'	31 (33.30%)	29 (33.70%)	0.100
6 - 10'	23 (24.70%)	11 (12.80%)	
>10	39 (41.90%)	46 (53.50%)	
Number of medication			
>than 5	66 (71.00%)	53 (62.80%)	0.316
≤5	27 (29.00%)	32 (37.20%)	

[Table/Fig-4]: Logistic regression for factors predicting medication adherence Distribution of clinical characteristics of the participants according to level of adherence Chi square test, *Significant at p<0.05, Pearson Chi-square Value

the complexity of the medical regimen such as, "do you ever feel hassled about sticking to your treatment plan" [9]. The scale is viable and simple, has psychometric adequacy, has importance to clinicians, significant in public health, and has ability to improve patient commitment [10,11].

Problem Areas in Diabetes Scale (PAID) : PAID is a 20-item survey, having a Likert-scale format and is used to assess the degree to which diabetes mellitus management and/or feelings about diabetes mellitus are problematic to patients [12]. PAID survey was developed as a measure of diabetes mellitus-related stress that could be useful in measuring the association between psychological adjustment to diabetes mellitus and adherence to self-care behaviours [13].

The PAID questionnaire was translated to Malay Language (national language of Malaysia) by language experts in Universiti Sains Malaysia (USM) and test on the reliability was conducted as suggested in study conducted by Khan et al., [14]. Eleven responders (medical doctors and pharmacists) working in a government setting in Malaysia were given the translated version of PAID questionnaire via emails. The results showed an internal consistency of PAID achieved (Cronbach's alpha = 0.95).

The reliability and validity of PAID Scale have been recognized for different culture and the instrument was also found open to change [15].

DATA ANALYSIS AND INTERPRETATION

Assessing Patient's Adherence using Morisky Medication Adherence Scale (MMAS): With MMAS, the degree of adherence to OHM was determined according to the score resulting from the sum of all the 8 questions. One point was given for each positive answer about adherence and a higher score means better adherence. For instance high adherence (8 points), average adherence (6 to < 8 points) and poor adherence (< 6 points). In this study, the low and

medium adherers (score below 8 points) were combined into a single group labeled as "low adherence" and another group (score 8 points) as "high adherence" when analysing the results. This is because two categories of adherence are easier to analyse [16]. Adherence rate was calculated by dividing the number of participants with the Morisky score range over the total number of participants [17]. Univariate analysis (Chi-square) was conducted in order to identify factors that affect medication adherence. Descriptive statistics was used to assess the distribution of patients' sociodemographic variables (age, gender, marital status, highest education level and income) and clinical characteristic variables (BMI, HbA1c, duration of T2DM, number/type complications and quantity of medicine). The variables were summarized into percentage, mode, median and standard deviation (SD). Meanwhile, complications of T2DM were grouped into the top three complications which are nephropathy, neuropathy and retinopathy. Chi square test was used to explore relationship between top three complications of diabetes mellitus namely: nephropathy, neuropathy and retinopathy.

Mann-Whitney Test was used to evaluate differences among disease states namely, BMI and number of medications and between adherence score and duration of diabetes mellitus Kruskal Wallis Test was used.

With regard to the continuous variable, correlation test was conducted with adherence score (as measured by the MMAS) and age (years) was investigated using Pearson product-moment correlation coefficient. Preliminary analysis was performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. When data does not meet the stringent assumptions of parametric techniques, Spearman rho correlation (ρ) was used to interpret the output. Pearson Chi-square value is presented in the Chi-square Tests with a significance level needs to be 0.05 or smaller to be significant ($p < 0.05$). Binary logistic regression was conducted to determine whether variable factors significantly predicted adherence status.

Assessing Quality of Life using PAID Scale: PAID scores were calculated using a five-point Likert-scale with options ranging from "0-not a problem" to "4-serious problem". Summing all item scores and multiplying by 1.25 result in an overall PAID score. A minimum score of 0 indicates no diabetes mellitus related distress. A maximum score of 100 indicates significant diabetes mellitus-related distress.

RESULTS

Descriptive Analysis: Two hundred and twenty three participants were approached which later on 39 and 5 participants were excluded because of incomplete medical record and refusal of participating consent, respectively. One hundred seventy nine patients were enrolled in this study. Upon completing the interview, medical record from the NCD clinic were retrieved. The demographic data is presented in [Table/Fig-1].

The participants were predominantly female (57.0%) and of Indian ethnicity (40.80%). 5.60% of participants hold a minimum of university degree and 34.10% had went through at least 11 years of schooling. The majority of participants had an education level till primary schooling level (6 years of schooling) (34.60%) and 24.60% didn't attend any formal school.

More than two-third of the participants, were classified as low income group (e.g., \leq USD300 or less; 72.60%). Most were married (64.80%) and 5 (2.80%) were single and 59 (33.30%) were widow/widower or divorced.

Medication adherence rates: Among all the participants, 86 (48.0%) were high-adherers and the rest were classified as low-adherer. Adherence and demographic variables for the study participants was analysed with descriptive analysis. The average score of adherence among the elderly participants was skewed to

the left (skewness -1.55, kurtosis 2.12) median 7.75 (IQR 6.50-8.00) indicating more patients scoring high points.

There was no significant association between adherence and age, $r = 0.098$, $n = 179$, $p = 0.190$.

[Table/Fig-2] shows the distribution of demographic and clinical characteristics of the participants according to level of adherence. A Chi-square test for independence indicated no significant association between demographic variables; namely gender, ethnicity, marital status, education level, and income (Malaysia currency 1 ringgit equal to USD 0.3).

Factors included were age, gender, ethnicity, marital status, education level, income and HbA1c [Table/Fig-3]. The participants were classified into two groups of adherence level based on the cut-off score in their completed MMAS (Highest score=8, lowest score=0) [17]. Two dependent variables were categorized according to the MMAS score, where a score of 6 to 8 was grouped as high adherer and a score of 0 to 5 was grouped as low adherer. When all seven predictors were included in the binary logistic model, only HbA1c was found to be significantly associated with adherence. The model as a whole explained between 7.90% (Cox and Snell R Square) and 10.60% (Nagelkerke R squared) of the variance in whether participants are low adherer or high adherer. The model fit was good (p -value = 0.283) and correctly classified 60.90% cases.

[Table/Fig-3] shows the result of the binary logistic regression analysis. Clearly, a negative association between HbA1c levels and adherence was identified where a 1% increase in HbA1c is associated with a 30% decrease in the likelihood of being adherent.

The Level of Adherence According to the Disease States (HbA1c Levels, BMI, number of Medications and Duration of T2DM):

[Table/Fig-4] shows the results of the Pearson correlation analysis between the disease states and adherence level. The factors included latest HbA1c level, Body Mass Index (BMI), duration of diabetes mellitus (years) and numbers of medication prescribed. Only HbA1c showed a significant correlation with adherence level ($df = 1$, $X^2 = 6.620$; $p = 0.010$). Using the Mann-Whitney test to differentiate the adherence scores among participants disease states, the findings showed no significant interactions for the main effects of BMI ($z = -1.376$, $p > 0.05$) and number of medications ($z = -1.509$, $p > 0.05$) with adherence score. A significant inverse interaction emerged between HbA1c and adherence ($z = -2.271$, $p < 0.05$). In addition, a Kruskal-Wallis test between adherence score and duration of T2DM, found a significant associations ($r = 8.675$, $p < 0.05$). In participants diagnosed as with T2DM for more than 10 years mean ranks of adherence score were significantly higher.

The Quality of Life of the Elderly T2DM Participants using the PAID Questionnaires:

The mean elderly T2DM PAID score was $6.30 \pm SD 8.50$. A significant inverse association was observed between PAID score and the level of adherence ($r = -0.175$, $p < 0.05$). A test with Mann-Whitney U test further revealed a significance difference in the PAID score and adherence level of low adherence; median (Md = 5.00, N = 93) and high adherence (Md = 1.25, N = 86), $U = 2967.00$, $z = -3.03$, $p = 0.002$, $r = 0.23$. Cohen's criteria [18] considered a very small effect of adherence on PAIDS. A Mann-Whitney U test revealed no significance difference in the PAID score of those HbA1c level is more than 6.50% (Md = 3.75, N = 114), $U = 3188.50$, $z = -1.574$, $p = 0.115$, $r = 0.12$.)

Complication of T2DM: 50.80% of participants have two or more complications and only 14.50% of participants have no recorded complication. Most participants suffer complication of T2DM. Retinopathy (35.20%), nephropathy (31.28) and neuropathy (27.93%) are the highest complication that was recorded among the participants. Other concomitant diseases found were diabetic foot ulcer (17.32%), heart failure (8.94%), stroke (5.03%), angina (2.23%), myocardial infarction (1.68%) and erectile dysfunction (1.68%). A chi-square test indicated no significant association between these complications and the adherence level; nephropathy

($df = 1$, $X^2 = -0.002$, $p > 0.05$), neuropathy ($df = 1$, $X^2 = -.705$, $p > 0.05$) and retinopathy ($df = 1$, $X^2 = 0.006$, $p > 0.05$).

DISCUSSION

It is essential to recognize predictors of adherence and to establish the relationships between adherences and health related quality of life in older adults (aged ≥ 60 y) with T2DM. Again, the expected proportion of people aged 60 and above in the year 2020 was expected to be 9.5% [19]. It is crucial to ensure patient's adherence of the prescribed medication in T2DM because of the strong correlation between adherence, patient outcomes, and treatment costs. A patient with T2DM medication adherence is a key ingredient of self-management [20]. This study is more exclusive for the elderly participants since earlier studies that assesses medication adherence using self-reported questionnaire did not focus on this group. Thus, the finding of a lower rate of adherence (48%) among elderly T2DM patients is of clinical importance since this can be used as a yardstick to improve disease management.

The result of the present study is lower than the World Health Organization (WHO) reported adherence to medication, which averages around 50% in developed countries, and worse in developing countries [21]. Similar reports from prospective studies of a systematic review of antidiabetic medication adherence revealed that many patients had poor adherence to oral antidiabetic medications [22]. Their results ranged from 67 to 85% and overall adherence rate was from 36 to 93% which is higher than that observed in this study [23]. Additionally, an adherence rate of 56% towards prescribed antihypertensive, antidiabetic and antiasthmatic medications was reported among out-patients attending a health clinic of the similar setting situated in the state of Melaka of Malaysia [24]. In agreement with that, another study conducted in seven health clinic of similar setting in the state of Selangor of Malaysia found out that 53% of the T2DM participants were nonadherent towards their antidiabetic medications [25]. Thus, adherence is a common problem in almost all patients with chronic diseases.

The mean age of participants, 68.50y, is similar with the Malaysia prevalence of T2DM by age group where the highest prevalence was in the 60-64y old [26]. Similar to other studies [22,23], the present study found that age and adherence to medication has no significant association. Inter-gender differences in adherence were demonstrated in a study where the participants consisted of approximately 40% Indian and 57% females. In the study by Letchumanan et al., they reported the prevalence rate of participants of Indians ethnicity with T2DM is 19.9% and this finding was almost twice than other major ethnicities. General global trend on the other hand reported T2DM prevalence to be somewhat higher in males (11.9%) than females(11.3%) [26].

The barrier to effective communication with the healthcare professionals was probably one of the reasons affecting adherence. With the lower literacy, education and counseling session at the health care facilities will be less effective. This finding contradicted with results by Bezie et al., regarding the association of educational level and medication adherence [27]. Furthermore, the study reported by Al-Qazaz found that patients with higher educational background can have better access to information, through internet, books, other sources of media and might be associated with their awareness and concern for adherence to medication [28]. It is also interesting to note that no inter-ethnic differences in adherence were found among Indians, Chinese and Malay participants (the three main ethnic groups in Malaysia). Although some studies suggest that ethnicity may affect adherence, several other reports found no significant association. It is possible that the lack of differences in the present study is the result of inadequate sample size and skewed distribution among the groups.

Sociodemographic features such as gender, ethnicity, marital status, education, and income as well as BMI were not statistically

significantly associated with adherence. Regardless of the reality that T2DM is a progressive disease, the present study showed that complication to T2DM does not significantly associate to adherence to medications. On the other hand, other studies reported that the option to take or not to take a medication as prescribed remained patient's personal choice [29,30]. Self-reported questionnaire usually present an overestimation of adherence for various reasons: first, they possibly depend on patients' own explanation or recollection of whatever recommendations was given by health care provider and, if acknowledged or accepted by patients', how much it has been followed. Secondly, in order to please health care providers or prevent unnecessary stigmatization patients may have a tendency to report higher levels of adherence [31].

In this current study, significant association between adherence and HbA1c levels was observed. Where the inverse HbA1c level ($p < 0.05$) indicated the lower in HbA1c value the higher adherence score. This result revealed that good glycemic control is associated with medication adherence. Earlier studies also confirmed that better T2DM control was significantly dependent on adherence to medication [32]. Al-Qazaz et al., concluded in their study that, glycemic control ($r = -0.505$) has more impact on patients' medication adherence than T2DM knowledge ($r = -0.390$) [28]. Previous studies that examined the effects of regimen complexity, drug type, and duration of treatment had shown inconclusive results. In this current study found a significant association between adherence and duration of T2DM. Those who were diagnosed since more than 10 y showed statistically significant higher adherence than those who were diagnosed since less than 10y. This finding is supported by Benner et al., [33] who concluded that independent predictors of poor long-term persistence are non-whites, lower income, older age, less cardiovascular morbidity, depression, dementia and occurrence of coronary heart disease. It is likely that other prevailing variables could also have accounted for the differences in adherence, for instance the social support, or satisfaction with the health service provided. In clinical practice, these important variables need to be assessed to predict good glycemic control.

In this study, mean PAID score among elderly T2DM was $6.30 \pm SD 8.50$. The finding of this is fourfold lower than the study conducted in San Diego, United States among Type 1 and Type 2 diabetes mellitus patients ($29.20 \pm SD 20.90$) [34]. Another study comparing the United States and the Dutch people, among type 1 and T2DM patients'; reported the mean PAID score for the patients in Netherlands and United States were $22.50 \pm SD 19.80$ and $27.80 \pm SD 23.20$ respectively [35]. These findings showed that participants in this present study had lower distress level. This study confirms that greater T2DM-specific emotional distress is associated with younger age ($r = -0.41$), female gender ($r = -0.42$) and higher HbA1c ($r = 0.15$) at $p < 0.05$ similar with previous findings [36]. A study conducted in Massachusetts, United States showed age and level of HbA1c, among T2DM patients, are important aspects of T2DM-related emotional distress similar to the findings in this present study [37].

The study by Polonsky et al., [13] observed weak and inconsistent correlations between T2DM emotional functioning, measured by PAID and blood glucose control. They mentioned that some patients may exercise very good control because they are emotionally distressed about long-term complication of T2DM. On the other hand, patients with a history of poor glucose control, but presently showing signs of improvement, may not be much distressed[13].

The result from the current study showed that; "worry about the future and possibility of serious complication" and "feeling scared thinking about living with T2DM" was most highly endorsed as a serious problem. However, these findings contradicts with previous studies [13,36] where patients ranked depressing feelings about food and eating as their greatest concerns.

CONCLUSION

A medication adherence rate of 48% was obtained among elderly T2DM patients treated in the primary care clinic in west coast of Peninsular Malaysia. HbA1c is found to be a relevant measure to assess patient glycaemic control and adherence. There appears to be no statistically significant relationships between adherence and sociodemographic characteristics among the elderly group of population. Adherence and T2DM related emotional distress are correlated with each other. These findings are similar to those reported in other Western countries.

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