COMPLIANCE ON ORAL ANTI-DIABETIC AGENTS AND ITS ASSOCIATED FACTORS AMONG ELDERLY WITH TYPE 2 DIABETES MELLITUS AT HOSPITAL UNIVERSITI SAINS MALAYSIA

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DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE

DEGREE OF MASTER OF MEDICINE

(FAMILY MEDICINE)

UNIVERSITI SAINS MALAYSIA
2017

ACKNOWLEDGEMENT

I would like to express my utmost thanks and gratitude to my supervisors for their advice, guidance and support in conducting this research project and completion of this dissertation as well as the whole duration of my training in family medicine MMED programme in the Department of Family Medicine, Hospital Universiti Sains Malaysia. I also like to thank other lecturers from Family Medicine Department, HUSM for their help and encouragement. My thanks also dedicated to Prof Dr. Mohamed Azmi Hassali, Professor of Social and Administrative Pharmacy, Universiti Sains Malaysia for the use of Malay version of Morisky Medication Adherence Scale (MMAS).

I would like to express my appreciation to Miss Mardhiah Kamaruddin for her willingness in helping me with SPSS and in data interpretation. Not forgetting to all respondents who had given their kind consent and patience in answering the questionnaires, all doctors and staff from Klinik Rawatan Keluarga, HUSM for their help throughout the study period.

Finally, my deepest gratitude to my husband, Zamrie Mansor, my childrens, my parents and my parents in law whose patience and encouragement has made the completion of this study possible.

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ABSTRACT

Objectives: This study aim to determine the percentage of compliance to oral anti-diabetic agent (OAD) and its associated factors among elderly with Type 2 Diabetes Mellitus attended Klinik Rawatan Keluarga (KRK) , Hospital Universiti Sains Malaysia (HUSM).

Methods: This is a cross sectional study involving 313 Type 2 Diabetes patients, age 60 years and above. Convenience sampling method was used to select patient who came to KRK, HUSM from March to August 2015. A validated Malay version of 8 items Morisky Medication Adherence Scale (MMAS) was used to assess medication adherence and Diabetic Family Behaviour Scale (DFBS) was used to assess family support. The sociodemographic and medical characteristics were obtained. Multiple logistic regression was used to evaluate the associated factors for compliance.

Results: The percentage of compliance to OAD among the elderly patients was 59.4%. Transportation to the clinic (p=0.022, OR:2.32, 95% CI:1.13,4.77) , HbA1c level (p=0.013, OR:0.51, 95% CI:0.29,0.87), supportive family behaviour (p=0.025, OR: 1.60, 95% CI:1.06, 2.43) and obstructive family behaviour (p=0.008, OR: 0.55, 95% CI:0.36, 0.86) were significant factors that associated with compliance.

Conclusions: The percentage of compliance among the elderly with Type 2 DM still low. Transportation to the clinic, HbA1c level, supportive family behaviour and obstructive family behaviour were significantly associated with compliance.

Keywords: *compliance, Type 2 diabetes, oral anti-diabetic agent, oral hypoglycaemic agents, elderly*

ABSTRAK

Objektif: Tujuan kajian ini adalah untuk menentukan tahap kepatuhan terhadap pengambilan ubat "anti-diabetic" (OAD) jenis tablet dan faktor-faktor yang berkaitan dengannya di kalangan warga emas dengan penyakit Kencing Manis Jenis 2 di Klinik Rawatan Keluarga (KRK), Hospital Universiti Sains Malaysia (HUSM).

Metodologi: Ini adalah kajian rentas yang melibatkan 313 orang pesakit Kencing Manis Jenis 2 berumur 60 tahun dan ke atas. Pemilihan sampel secara konvinien telah dilakukan untuk memilih peserta yang datang ke KRK, HUSM dari bulan Mac hingga Ogos 2015. Borang soal selidik "Morisky Medication Adherence Scale" (MMAS) dalam Bahasa Malaysia telah digunakan untuk menguji tahap kepatuhan terhadap ubat dan "Diabetic Family Behaviour Scale" (DFBS) pula digunakan untuk mengetahui tentang penglibatan keluarga. Ciri-ciri sosiodemografi dan faktor klinikal diperolehi. Data yang diperolehi melalui sesi temuramah ini telah dianalisa menggunakan regresi logistik berganda bagi mengetahui faktor-faktor berkaitan dengan kepatuhan terhadap pengambilan ubat.

Keputusan: Kepatuhan terhadap ubat OHA di kalangan warga emas adalah 59.4%. Cara pengangkutan (p=0.022,OR: 2.32, 95% CI:1.13,4.77), tahap HbA1c (p=0.013,OR: 0.51, 95% CI:0.29,0.87), tingkahlaku keluarga yang menyokong (p=0.025, OR: 1.60, 95% CI:1.06, 2.43) dan tingkahlaku keluarga yang menghalang (p=0.008, OR:0.55, 95% CI:0.36, 0.86) adalah faktor-faktor yang berkaitan dengan kepatuhan terhadap ubat OHA jenis tablet.

Kesimpulan: Kepatuhan terhadap ubatan di kalangan warga emas yang menghidapi penyakit Kencing Manis Jenis 2 masih rendah. Cara pengangkutan ke klinik, tahap HbA1c, tingkahlaku keluarga yang menyokong dan tingkahlaku keluarga yang menghalang menunjukkan kaitan yang signifikan dengan kepatuhan terhadap ubat.

Katakunci: *kepatuhan, Kencing Manis Jenis 2, ubat kecing manis jenis tablet, warga emas*

INTRODUCTION

Diabetes mellitus is one of the most significant public health issues and its incidence keeps increasing globally (1). There are many factors that contribute to this increasing trend, for example, population growth, aging population, urbanization and increase in the prevalence of obesity and physical inactivity (2, 3).The number of diabetic patients is expected to increase to 642 millions in 2040 whereby South East Asia countries will have the highest prevalence (3). Recently, in Malaysia, it was reported that the prevalence of diabetes mellitus was 17.5% in 2015 (4). Among those people with diabetes, complications like lower limb amputation, stroke and dialysis are reported as 4.3%, 3.4% and 1.6% respectively. These figures also highlight that there are a lot of cost need in managing the disease itself with the various complications (5). Therefore, several actions have to be done to tackle these problems such as lifestyle modification in term of diet and physical activity, and medications in order to control blood glucose level (2). The use of medication is an effective method to lower the blood glucose level. However, C. Everett Koop, M.D, an American paediatric surgeon ever said that "the drugs do not work in patients who don't take them". So, one of the factors that determine the success of the treatment is the level of compliance.

Compliance or adherence to the medication was defined as patient acts in accordance with the prescribed interval and dose of a dosing regimen (6). A systemic review of 3166 articles, 27 studies included and it was found that the prevalence of good compliance among Type 2 diabetic patients was widely range from 38.5% to 93.1% (7). This result was consistent with other studies among other chronic diseases such as asthma (8), chronic obstructive pulmonary disease (COPD) (9), heart failure (10) and hypertension (11).

Apart from that, there were various important factors that associated with compliance in the previous studies. Compliance is known to be associated with many factors such as age (12), gender, socioeconomic (13), duration of disease (14, 15), comorbidity (16), choice of treatments (17) and accessibility of care (7). Furthermore, family support also played an important role in compliance (18, 19).

In Malaysia, elderly was noted to be a growing population with reducing of fertility and longer life expectancy (20). This age group was shown to have a higher prevalence of diabetes and with another chronic disease (23). Elderly with diabetes is also known to have multiple morbidities from serious complications of diabetes. As a result, the cost of managing diabetes and its complication is huge and is causing significant impact to the health economic and health expenditure of the country (21). One of the important reason for developing complications is the noncompliance to the treatment. Medication noncompliance reduces the effectiveness of the treatment. In elderly, medication compliance is very challenging due to multiple prescriptions, the deterioration of memory and physical limitations such as visual acuity, hearing, mobility, etc.

Previous studies showed that medication compliance among elderly with chronic disease was 30.4% and 47.5% in Italy (22) and Korea (23) respectively. Nonetheless, studies on medication compliance among elderly with diabetes were limited. There is only one study on compliance among elderly diabetes in the literature review which was conducted in Korean in 2010 (24). The study showed compliance among elderly in the tertiary hospital was 61.1% and 43.2% in private clinic. Local studies among type 2 diabetes also not focus on elderly with type 2 diabetes (16, 25). Therefore, it is necessary to determine the associated factors for compliance among elderly with type 2 diabetes in order to plan more effective strategies to improve compliance. Apart from

that, the role of family involvement also being tested in this study in order to see any contribution of family support to the compliance of medication. Many worldwide studies showed that family support had a significant association with compliance to the medication (26-31). However, there were limited local studies showed the association between family support and compliance to the medication. Thus, this study was conducted to determine the percentage of compliance to the oral anti-diabetic agent (OAD) among elderly with Type 2 Diabetes Mellitus and its associated factors.

LITERATURE REVIEW

Measuring compliance

So far, there are no gold standard method to measure compliance. There are many methods used to measure the compliance level either direct or indirect methods (32). Direct methods involve directly observed therapy, measurement of the level of medicine or metabolite in the blood and measurement of biologic marker in the blood. Meanwhile, indirect methods are patient self-report, pill counts, pharmacy fill data, electronic medication monitoring, and assessment of patient's clinical response. Each method has their own advantages and disadvantages.

Measurement of concentrations of a drug is the most accurate method but it is invasive, expensive and can be a burden to the health care provider. Beside that, this direct method unable to be applied to all kind of diseases. Indirect methods tend to overestimate the compliance and underestimate the noncompliance (7). Rates of prescription refills were noted to be commonly used but need a close pharmacy system (32). Medication Event Monitoring (MEM) can give precise record when patient open the medication bottles however, patient may not take the medications (33).

Self-report questionnaires also commonly used in any previous studies. Morisky Medication Adherence Scale (MMAS) 8 items is one of the popular method used in previous studies (34, 35) and was validated by various languages including Malay Language (8, 17, 36, 37). There are also other types of questionnaire in assessing compliance including MMAS 4 items (24), Hill-Bone compliance scale (38), ASK-20 (39), Beliefs about Medicines Questionnaires (BMQ) (40) and Medication Adherence Rating Scale (MARS) (41). Apart from that, Malaysian Medication Adherence Scale (MALMAS) (42) and Medication Compliance Questionnaire (16) are from local study. Questionnaire self report method is simple, inexpensive, and the most convenient method in clinical setting (32). However, MMAS tend to be easier to use with not much items and easier choice to select especially in elderly age group.

Medication compliance and its factors

Various studies were done previously among patients with chronic diseases such as heart failure, Chronic Obstructive Pulmonary Disease (COPD), hypertension, and diabetes.

In Candesartan in Heart Failure Assessment of Mortality and Morbidity (CHARM) programme among 7599 of symptomatic chronic heart failure patients, 80% was compliant and male gender was found to be more compliant. Age, severity of heart failure, number of medications, and smoking status were not significant association with compliance (10). In Egypt, among patients with persistent bronchial asthma, There was 50% of compliance by using Medication Rating Scale. The older age of the patient and who had health education were noted to be more compliant to the

asthma therapy (8). Gender and level of education were found to be not significant in this study.

However, a study in Budapest Hungary, used to post questionnaire to 250 COPD patients and found about 58% of patients were compliant to their medications. Age, current smoking status, number of drugs, number of daily drug doses and quality of life noted to be significant predictors for compliance (9). Gender, severity of the illness, lung function and medication cost per month were not associated with compliance.

Meanwhile, Nur Sufiza Ahmad and her group found that 47% of Type 2 Diabetes patients were compliant to their medications. Reported that age, medication knowledge and comorbidities were significant predictors of noncompliance among 557 patient with type 2 diabetes mellitus at primary health clinic in Hulu Langat, Selangor (16). Gender, race, level of education, duration of diabetes, number of drugs taken per day and pattern of antidiabetic treatment were not associated with compliance.

A French population-based study known as ENTRED study among 3,637 Type 2 Diabetes patients, reported that only 39% of them who were compliant with their medications (12). Age, financial difficulties and employment were associated with compliance. Other factors such as marital status, complementary health insurance, bodymass index (BMI), smoking status and the presence of complications were not significant association with compliance. Another study in Ethiopia using a systemic random sampling method among 270 Type 2 diabetic patients noted 63% of the patients compliant to their medication, using self-report questionnaire (15). This study showed that single status was significantly associated with compliance. Age,

education level, comorbid and number of medications were reported not associated with compliance.

Marital status also noted to be a significant influence on patient's tendencies to have better compliance by a study among 270 patients with type 2 diabetes attending the diabetic clinic in Adama Hospital (15). Other than that, the patient with less than 5 years duration of diabetes was found to be more compliant to their medication in that study. Compliance rate in that study was 72.2% using a structured interview with new developed questionnaire. This result is in agreement with another study from Tayside, Scotland (43). In that study, shorter duration of diabetes and being young were noted to be significant for compliance. Age, gender, comorbidity and number of medications were not significant.

Meanwhile, a study in Uganda on compliance to diabetic medications among 521 patients also agreed that duration of diabetes and medical knowledge were significant association with compliance (14). In that study, 83.3% of the patients were compliant to their medications. Compliance was measured using self report compliance index. Other factors such as education level, marital status, occupation and type of diabetic medications were not significantly associated with compliance.

Result from Uganda was in consistent with a study in New South Wales, Australia (13). That study used posted 8 item Morisky Adherence Scale which reported that 53.6% of Type 2 diabetic patients were compliant. Medical knowledge about diabetes were noted to be significant while duration of disease, complications, type of doctor looking after diabetes and frequency of visiting doctor for diabetes were not significant.

One study in Korea found that there was 61.1% of their elderly comply to their medication (24). Financial level, drug storage and self efficacy were found significantly associated with compliance. The compliance to the medication among elderly in latest studies were in a range from 39% to 48% in chronic disease (22, 23, 44, 45).

Family support and compliance

Social support including family support can be divided into 3 major types (27). The structural support such as marital status, living arrangement and social network, the instrumental support such as picking up prescriptions, transportation, filling pill boxes, reading labels and physical assistance. The third type was emotional support such as encouragement, listening, attachment, nourishment and spiritual. The family support was consistently associated with greater medication compliance (26-31).

A study which was conducted in Bangladesh found that the patients who had good family support tended to have good glycaemic control. Compliance to diabetic management was the contribution to the good glycaemic control . This study was done among 144 patients with type 2 diabetes mellitus. Spouse was the most caring person noted in this study. On the other hand, about 14.6% of the patients who did not have any support in which majority of them noted to have poor glycaemic control (26).

A population based study or known as the ENTRED study in French in 2007 also came out with similar result. Lack of family or social support had significantly associated with noncompliance (12). A study by Lindsay among type 2 diabetes also gave a similar result showed that nonsupportive family behaviour was associated

with noncompliance to medications (28). Hara and her group studied about family support and compliance. They found a significant association between compliance and family support. Family support also correlates well with good HbA1c achievement among the patients (46).

Eventhough there was various study worldwide on family support and compliance to medication, Malaysia noted to have limited data on family support and medication compliance. A cross-sectional study with convenience sampling among Type 2 Diabetes patients in Penang was conducted to investigate any association of knowledge and medication compliance with glycaemic control (25). Patients with higher diabetes knowledge and good medication compliance were reported significant predictors for good glycaemic control.

OBJECTIVES

General objective

To determine the compliance to the oral ant-diabetic agent (OAD) and its associated factors among elderly with Type 2 Diabetes Mellitus attended Klinik Rawatan Keluarga Universiti Sains Malaysia.

Specific objectives

1. To determine the proportion of compliance to OAD among elderly in Type 2 Diabetes Mellitus.

2. To determine the associated factors for compliance to OAD among elderly in Type 2 Diabetes Mellitus.

Research hypothesis.

The compliance to OAD among elderly with Type 2 Diabetes Mellitus attended Klinik Rawatan Keluarga Universiti Sains Malaysia was associated with specific sociodemography and family support.

Operational Definitions

1. **Elderly** is defined as patient who is 60 years and above (47).

2. **Transportation** means how participants usually come to the clinic. Initially it was not categorized but than later it was divided into two group either on their own or with their relative. The grouping was done for further analyzed.

3. **Marital Status** is defined as current status of the participant. This initially was group into 4 types as married, widow, divorcee and unmarried but later were collapse into two group either married or unmarried. It mean that participant who are single during the interview was considered unmarried either they are never married or widow/divorcee.

4. **Tertiary** education level means any formal education level after secondary education (48).

5. **Pensioner** means who had retired and received pension (49).

6. **Monthly household income (MHI)** is defined as total monthly income of the participants and monthly income of other members in the household. Initially MHI was not categorized, later it was categorized into 2 groups according to poverty line incomes in Peninsular Malaysia in 2012 as reported in Labour and Work Statistic 2015 by Ministry of Human Resource (50). Below poverty means MHI of RM 830 or less and non-poverty means MHI of more than RM 830.

7. **Compliance** is defined as the extent to which a person's medication use behaviour coincides with medical or health advice, and persistence as the duration of time from initiation to discontinuation of the the therapy (6). In this study, compliance is based on the total score of > 6 by Morisky Medication Adherence Scale (MMAS).

8. **Comorbid** is defined as other illness apart from diabetes. Elderly have many comorbidities. In this study, hypertension, hyperlipidaemia or both only included since there are various of comorbid and our initial data noted both two disease are the common.

9. **HbA1c level** in elderly is based on our new Clinical Practice Guideline (CPG) on Management of Type 2 Diabetes Mellitus 5th Edition , March 2015. HbA1c level obtained for the past 6 month since CPG suggested at least 3 monthly monitoring HbA1c level.

i) HbA1c ≤ 7% = Good blood sugar control in elderly

ii) HbA1c > 7% = Poor blood sugar control in elderly

10. **Family support** is defined according to Diabetes Family Behaviour Scale (DFBS) which was translation to Malay language for the purpose of this study. It was divided into:

\i) Supportive Family Behaviour include question 1, 4, 7, 8, 9, 11, and 12 in the DFBS

ii) Obstructive Family Behaviour include question 2, 3, 5, 6, 10, and 13 inthe DFBS

METHODOLOGY

Study design

This is a cross sectional study and the data collection started from March to August 2015.

Study area

Universiti Sains Malaysia Hospital is one of the tertiary hospitals that located about 6 kilometres from Kota Bharu which is the capital city of Kelantan. Besides in patient management, it also offers out patient services. It consists of Family Medicine Clinic, known as KRK, Specialist clinics and Accident and Emergency Unit. This study was conducted in KRK.

Population and sample

Reference population

Patients with Type 2 Diabetes Mellitus in Kota Bharu, Kelantan.

Source population

Patients with Type 2 Diabetes Mellitus attending Klinik Rawatan Keluarga, Universiti Sains Malaysia Hospital from March to August 2015.

Sampling Frame

Patients with Type 2 Diabetes Mellitus in Klinik Rawatan Keluarga (KRK) HUSM who fulfilled the inclusion and exclusion criteria.

Inclusion criteria

1. Type 2 DM age 60 years and older
2. On at least 1 oral anti-diabetic agent (OAD)
3. On OAD for at least for 12 months already

Exclusion criteria

1. Cognitive impairement
2. Mental illness
3. Insulin only treatment

Sampling Method

Initial systemic random sampling was changed to convenience sampling due to limited number of participants.

Sample size

Sample size was calculated for all objectives. The biggest calculated sample size was taken as the sample size.

Objective 1 was to determine the percentage of good compliance to OAD among elderly in Type 2 Diabetes Mellitus at Universiti Sains Malaysia Hospital. The sample size was calculated using single proportion formula;

$$n = \frac{(Z\alpha)^2 \times P(1-P)}{\Delta^2}$$

n = minimum required sample size

$Z\alpha$ = value of standard normal distribution = 1.96

Δ = absolute precision = 0.1

P = prevalence of compliance among adults patient (> 60 years old) with Type 2 Diabetes Mellitus = 0.5 (16)

The minimum sample size was 96. However, after considering the non-response rate of 20%, the calculated sample size was 115.

Objective 2 was to determine the associated factors for compliance to OAD among elderly in Type 2 Diabetes Mellitus at Universiti Sains Malaysia Hospital. The sample was calculated using Power and Sample Size Calculation software for comparing two proportions.

P_0 = proportion of exposure in noncompliance

P_1 = proportion of exposure in compliance

m = ratio of noncompliance to compliance

Variables	P^0	P^1	*m*	Min sample	Citation
Age	0.44	0.6	1	304	(16)
Household Income	0.30	0.5	1	223	(18)
Comorbid	0.51	0.65	1	96	(16)
Education level	0.40	0.60	1	232	(51)
Duration of DM	0.46	0.53	1	77	(16)

Objective 2 for the variable age yielded the biggest sample size for this study. Therefore, taken as the study sample. The minimum sample was 304 and after considering 10% nonresponsive rate, the calculated sample size was 334.

Research tools

The case report form consist of 4 parts;

a) Socio-demographic data
b) Medical characteristics
c) Malay version Morisky Medication Adherence Scale (MMAS) 4 parts
d) Diabetic Family Behaviour Scale (DFBS)

i) Socio-demographic data composed of 7 questions regarding age, sex, marital status, education level, employment, monthly household income and transportation to the clinic

ii) Medical characteristics consisted of 4 questions regarding duration of their diabetes, HbA1c level, comorbidity, type of oral anti-diabetic agent (OAD)

iii) Morisky Medication Adherence Scale (MMAS)

The original Morisky Medication Adherence Scale which was developed by Morisky et al. in Los Angeles (34). It consisted of 8 questions with answer "Yes" or "No" for question 1 to 7 but in scale from "never" to "almost of the time" for question 8. Each answer "Yes" got 0 score and

"No" got 1 score except for question 5. In question 8, the score will be 1 for "never" and 0 for the other answers. Total score of more than 6 was considered as compliance. This study used the questionnaire that was obtained from published validation paper of Malay Version of Morisky Medication Adherence Scale (MMAS) , which was developed and validated by Harith Al-qazaz et al in 223 diabetes patients who attended Diabetes Clinic of Penang General Hospital, Penang. The Malay version MMAS is a validated self-reported questionnaire with sensitivity and specificity, were 77.61% and 45.37% respectively with Cronbach's α was 0.675 (36).

iv) Diabetes Family Behaviour Scale (DFBS)

This questionnaire was adapted from a study done by Lorraine C. Schafer et al in 1986. In that study, DFBS was used among insulin-dependant diabetes mellitus (IDDM). It consists of 16 items regarding family support toward diet, glucose, insulin and exercise. It has Cronbach α of 0.73 for the supportive family behaviour domain and 0.43 for the obstructive family behaviour domain (52). The 16 items DFBS consist of specific family behaviour in the past month on a scale of 1 = never to 5 = once a day. There were 9 items in supportive family behaviour and 7 items in obstructive family behaviour domain.

However, in this study, some changes were made especially the items that involved insulin injection. The items like " carry something sugary in the case of low blood sugar" (supportive family behaviour domain), "

suggest things that might help you take insulin on time" (supportive family behaviour domain) and "critisize you for not recording blood sugar test results"(obstructive family behaviour domain) were removed. Finally, there were only 13 questions with 7 items supportive family behaviour and 6 items for obstructive family behaviour. The list of questions represented specific family behaviour as in Table 1. A supportive family behaviour domain range from 7 to 35 and obstructive family behaviour score range from 6 to 30. The items of supportive family behaviour domain and obstructive family behaviour domain were averaged to create two subscales ranging from 1 to 5, with higher scores indicating more supportive or obstructive behaviours, respectively.

The questionnaire was translated into the Malay language to use in this study. Forward and backwards methods involving two different bilingual teachers were done. Then, the translations were compared and discussed for final preliminary version. Two of Family Medicine physicians were involved in content validity. Subsequently, the preliminary testing was done among 10 diabetic patients at Klinik Kesihatan Pengkalan Chepa for face validity and to estimate the duration to complete the questions. Face validity was satisfied and no item was dropped.

The whole set of questionnaire took about 10-15 minutes to be completed.

Ethical considerations

This study protocol was approved and accepted by Research and ethics Committee, School of Medical Science, University Sains Malaysia, Human Ethic Committee on 12th March 2015 (USM/JEPeM/1406234).

Data collection procedure

Type 2 Diabetes Mellitus patients who came for follow up at Klinik Rawatan Keluarga HUSM were recruited in this study. The inclusion and exclusion criteria were applied. The respondent who did not give their consent will be considered as refused to participate. Informed consent will only be obtained if patient agrees to participate in this study. They were brought to a comfortable and quiet room and then face to face interview was conducted. Their medical folder was reviewed for HbA1c level and type of medications.

Data entry and analysis

Data entry and analysis were done using the SPSS software for windows version 22. Data entry, exploration and cleaning were done before analysis. Socio-demographic and clinical characteristics were analysed using descriptive analysis. The categorical variables were presented as frequency and percentage. Numerical variables were expressed using mean and standard deviation. The categorical variables were sex, marital status, education level, employment, monthly household income, transportation to the clinic, HbA1c level, comorbidity and oral anti-diabetic agent (OAD) pattern. Numerical variables were age, duration of diabetes (years), supportive family behaviour score and obstructive family behaviour score.

Objective 1 was analysed using descriptive statistic and objective 2, the associated factors were analysed by multiple logistic regression. The significant p value was set at < 0.05 with 95% confidence interval.

There was no significant interaction effect among independents variables and the model assumption was fit. The assumption was checked and found no violation.

TITLE PAGE

Article title: Compliance on Oral Anti-Diabetic Agent and Its Associated Factors Among Elderly With Type 2 Diabetes Mellitus at Hospital Universiti Sains Malaysia

Running Head: Compliance to anti diabetic agent at Hospital Universiti Sains Malaysia

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ABSTRACT

Objectives: This study aim to determine the percentage of compliance to oral anti-diabetic agent (OAD) and its associated factors among elderly with Type 2 Diabetes Mellitus attended Klinik Rawatan Keluarga (KRK) , Hospital Universiti Sains Malaysia (HUSM).

Methods: This is a cross sectional study involving 313 Type 2 Diabetes patients, age 60 years and above. Convenience sampling method was used to select patient who came to KRK, HUSM from March to August 2015. A validated Malay version of 8 items Morisky Medication Adherence Scale (MMAS) was used to assess medication adherence and Diabetic Family Behaviour Scale (DFBS) was used to assess family support. The sociodemographic and medical characteristics were obtained. Multiple logistic regression was used to evaluate the associated factors for compliance.

Results: The percentage of compliance to OAD among the elderly patients was 59.4%. Transportation to the clinic (p=0.022, OR:2.32, 95% CI:1.13,4.77) , HbA1c level (p=0.013, OR:0.51, 95% CI:0.29,0.87), supportive family behaviour (p=0.025, OR: 1.60, 95% CI:1.06, 2.43) and obstructive family behaviour (p=0.008, OR: 0.55, 95% CI:0.36, 0.86) were significant factors that associated with compliance.

Conclusions: The percentage of compliance among the elderly with Type 2 DM still low. Transportation to the clinic, HbA1c level, supportive family behaviour and obstructive family behaviour were significantly associated with compliance.

Keywords: *compliance, Type 2 diabetes, oral anti-diabetic agent, oral hypoglycaemic agents, elderly*

Introduction

Diabetes mellitus is one of the most significant public health issues and its incidence keeps increasing globally (1). There are many factors that contribute to this increasing trend, for example, population growth, aging population, urbanization and increase in the prevalence of obesity and physical inactivity (2). In Malaysia, it was reported that the prevalence of diabetes mellitus was 17.5% in 2015 and caused many complications which lead to increase financial burden to the country (3). A few actions have to be done to tackle these problems such as lifestyle modification and efficient treatment in order to control blood glucose level. The use of medication is an effective method to lower the blood glucose level. However, compliance is an important element for its success.

Compliance or adherence to the medication was defined as patient acts in accordance with the prescribed interval and correct dosing regimen (4). There was no gold standard method to measure compliant (5). Previous studies used many methods to measure compliance such as self-report, pill count, electronic medication monitoring, measurement of drug concentration and measurement of a biologic marker in the body. On the other hand, self-report or questionnaire is commonly used because it is simple and easy as well as greater sensitivity and specificity (5-8).

Compliance is a challenging issue in dealing with a chronic disease such as diabetes. A systemic review of 3166 articles, 27 studies included and it was found that the prevalence of compliance to medication among Type 2 diabetic patients was ranging from 38.5% to 93.1% in Egypt and Netherlands respectively (9). This result was consistent among other chronic diseases such as asthma (10), chronic obstructive pulmonary disease (COPD) (11), heart failure (12) and hypertension (13). This wide

range of compliance results in chronic disease especially diabetes shows that compliance is still not being addressed effectively and the percentage varies greatly from country to country. Compliance is known to be associated with many factors such as age (14, 15), gender, socioeconomic (16), duration of disease (17, 18), comorbidity (19), choice of treatments (20) and accessibility of care (9).

In Malaysia, elderly was noted to be a growing population with reducing of fertility and longer life expectancy(21). This age group was shown to have a higher prevalence of diabetes and with another chronic disease (22). Elderly with diabetes is also known to have multiple morbidities from serious complications of diabetes. As a result, the cost of managing diabetes and its complication is huge and is causing significant impact to the health economic and health expenditure of the country (23). One of the important reason for developing complications is the noncompliance to the treatment. Medication noncompliance reduce effectiveness of the treatment. In elderly, medication compliance is very challenging due to multiple prescription, the deterioration of memory and physical limitations such as visual acuity, hearing, mobility, etc.

Previous studies showed that medication compliance among elderly with chronic disease was 30.4% and 47.5% in Italy (22) and Korea (24) respectively. Nonetheless, studies on medication compliance among elderly with diabetes was limited. Study among elderly with diabetes which was conducted in Korean showed compliance among elderly in the tertiary hospital was 61.1% and 43.2% in private clinic (25). Local studies among type 2 diabetes also not focus on elderly with type 2 diabetes (19, 26). Therefore, it is necessary to determine the associated factors for compliance among elderly with type 2 diabetes in order to plan more effective strategies to improve compliance. Apart from that, the role of family involvement also being tested in this

study in order to see any contribution of family support to the compliance of medication. Many worldwide studies showed that family support had a significant association with compliance to the medication (27-32). However, there were limited local studies showed the association between family support and compliance to the medication. Thus, this study was conducted to determine the percentage of compliance to the oral anti-diabetic agent (OAD) among elderly with Type 2 Diabetes Mellitus and its associated factors.

Material and Methods

A cross-sectional study was conducted for a period of 6 months from March 2015 to August 2015 at Klinik Rawatan Keluarga (KRK), Universiti Sains Malaysia Hospital (HUSM).

Participants

A total of 334 patients participated in this study, by using a two proportion formula and after considering 10% dropout. The inclusion criteria were Type 2 DM age 60 years and older, on at least 1 oral anti-diabetic agent (OAD) for at least for 12 months. The exclusion criteria were cognitive impairment, mental illness and who was on insulin only for their diabetic treatment.

Assessment of compliance

The original Morisky Medication Adherence Scale (MMAS) was developed by Morisky et al. in Los Angeles (6). It consisted of 8 questions and answer "Yes" or "No" for question 1 to 7 but in scale from "never" to "almost of the time" for question 8. Each answer "Yes" got 0 score and "No" got 1 score except for question 5. In question 8, the