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Factors Associated with HbA_{1c} Levels in Poorly Controlled Type 2 Diabetic Patients in North-East Malaysia

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Factors Associated with HbA_{1c} Levels in Poorly Controlled Type 2 Diabetic Patients in North-East Malaysia

Nor Azlina A. Rahman[1], Aziz Al-Safi Ismail[1], Nor Azwany Yaacob[1], Lin Naing[2]

ABSTRACT

Objective: **A study was conducted at all the health centres in Kelantan in North-East Malaysia to determine the common factors associated with poor controlled of type 2 diabetic patients.**

Design: **A cross-sectional study**

Materials and Methods: **A total of 208 patients with poor diabetic control (HbA_{1c} levels of more than 6.5%) were selected by stratified random sampling from all health centres in Kelantan. Socio-demographic data, physical examination, and fasting blood were taken from the patients to determine the related associated factors using multiple linear regression.**

Results: **The levels of HbA_{1c} in the poorly controlled diabetic patients were significantly associated with fasting blood glucose (*b*=0.236, 95% CI=0.189, 0.283), educational level (primary education: *b*=-0.965, 95% CI=-1.550, -0.380; secondary and tertiary education: *b*=-0.625, 95% CI=-1.228, -0.021), marital status (*b*=0.933, 95% CI=0.426, 1.440) and patients receiving their care in health centres with Family Medicine Specialist (*b*=-0.495, 95% CI=-0.913, -0.076).**

Conclusion: **Fasting blood glucose and being married were associated with higher levels of HbA_{1c}, while having had formal education and receiving diabetic care in health centres with Family Medicine Specialist were associated with lower levels of HbA_{1c} in poorly controlled type 2 diabetic patients in Kelantan.**

KEY WORDS

type 2 diabetes, poor glycaemic control, associated factors, HbA_{1c} levels

INTRODUCTION

Diabetes mellitus is one of the commonest chronic non-communicable diseases globally, causing high morbidity and mortality. Worldwide prevalence of type 2 diabetes is increasing, and in Malaysia it raised from 0.6% in 1960, to 2.1% in 1982, 6.3% in 1986, and 8.3% in 1996 (Ismail and Gill, 1999, Rugayah *et al.*, 1999, Zaini, 2000).

Majority of diabetic patients in Malaysia had poor glycaemic control, with 88% of them had HbA_{1c} levels of more than 6.5% and 86% had fasting blood glucose (FBG) levels of above 6.1% (DCDCP, 1997). In Kelantan, 73% of diabetic patients in Hospital Universiti Sains Malaysia (HUSM) had HbA_{1c} levels of more than 7%, and 60% had FBG levels of above 7.2 mmol/L (Eid *et al.*, 2003). Another study done in Kelantan reported that 85.7% of the patients had HbA_{1c} levels of more than 7.5%, with the mean HbA_{1c} levels of 9.9% (Suhaiza *et al.*, 2004). As a result, many patients end-up with chronic and serious complications. A study done in poorly controlled diabetics in Kelantan showed that 20.6% of them had nephropathy, 9.8% had neuropathy, 8.2% had retinopathy, 2.8% had foot ulcer and 2.4% had coronary heart disease (CHD) (Fauziah and Suhaiza, 2004). Earlier study done for Malaysia however showing higher prevalence of complications with 58% of the diabetic patients had neuropathy, 53% had retinopathy, 12% had foot ulcer and 9% had CHD (DCDCP, 1997).

Good glycaemic control can prevent or delay diabetic complications and reduce the cost of managing patients. The United Kingdom Prospective Diabetic Study (UKPDS) showed that each 1% reduction in HbA_{1c} levels was associ-

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ated with reduction in the risk of 21% deaths related to diabetes, 14% myocardial infarction and 37% microvascular complications (Stratton *et al.*, 2000). A study showed significant increase in medical care charges for every 1% increase in HbA_{1c} levels above 7% (Gilmer *et al.*, 1997). Studies done on factors associated with glycaemic control reported conflicting results (Ferrannini *et al.*, 1992, Blaum *et al.*, 1997, Nichols *et al.*, 2000, Schectman *et al.*, 2002, Eid *et al.*, 2003, Rekeneire *et al.*, 2003, Suhaiza *et al.*, 2004). This could be due to the difference in the source population and methodology used, categorisation of the patients' characteristics, and the difference in the classification of poor and good glycaemic control. Our study however was trying to determine the factors associated with HbA_{1c} levels in only poorly controlled diabetic patients.

MATERIALS AND METHOD

Study population

This study was conducted at all health centres (HC) in Kelantan in North-East Malaysia from August till October 2005. Only poorly controlled type 2 diabetic patients registered in the related HC aged 18 to 75 years old were selected for this study, except those who were having acute illness which need hospitalization three months before and during the study period and those on haemodialysis. HbA1c levels of more than 6.5% were taken as poor glycaemic control (Asian-Pacific Type 2 Diabetes Policy Group, 2002, CPG Task Force, 2004).

Methods

This is a cross-sectional study to determine the factors associated with HbA_{1c} levels in poorly controlled type 2 diabetic patients in Kelantan. Selection of subjects was by proportionate stratified random sampling by the HC. Patients who were chosen to participate in this study gave their written consent. Socio-demographic data and diabetic history were obtained from subjects using interviewed questionnaire. The education level was classified into no formal education ever received, having had primary education (primary school), and having had secondary (secondary school) and tertiary education (university or other higher institution). Marital status was divided into married (currently married) and others (either single, divorced or widowed). Current smokers were those who were still smoke currently, ex-smokers were those who previously smoked but had stopped at least one month prior to the study and non-smokers were those who never smoke before. Diabetic history included duration of diabetes and family history of diabetes.

Physical measurements were taken from subjects for blood pressure and body mass index (BMI). BMI was calculated as weight in kilograms divided by height in meter squared (kg/m^2). The weight of the subjects was measured using Seca™ weighing machine to the nearest 0.5 kilogram with subjects wearing light clothing and without shoes on. The blood pressure was measured in millimeter mercury (mmHg) using Omron™ automatic blood pressure monitor which used oscillometric method and validated to $\pm$ 3 mmHg. Three measurements were taken from each subject's right arm with the intervals of at least one minute. Average from the last two measurements was taken as the subjects' blood pressure. Other conditions which can affect the subjects' blood pressure were also observed. The subjects were asked to sit comfortably and the arms were supported at the heart level. The subjects were made sure to be rested at least five minutes before first measurement. No venepuncture was done immediately before taking the blood pressure measurement (PAHI, 2003).

The subjects were asked to fast overnight about 8-14 hours (WHO, 1999) the night before the data collection to get fasting blood from each subjects. The blood were analyzed in a commercial laboratory for HbA_{1c} levels, FBG and fasting lipid profile including total cholesterol (TC), triglycerides (TG), high density lipoprotein cholesterol (HDL) and low density lipoprotein cholesterol (LDL). The blood taken was kept in the ice-box for preservation before reaching the laboratory in view of the distance of the HC from the laboratory which was situated in the town of Kota Bharu, the capital city of Kelantan.

About two milliliters (ml) of the blood was put into tube containing EDTA to prevent it from clotting. This is for the analysis of HbA_{1c} using ion-exchange high-performance liquid chromatography by the D-10™ Haemoglobin A_{1c} Program. For the measurement of blood glucose, 1.5 ml of the blood was put into tube containing fluoride (WHO, 1999). The fluoride would preserve the glucose before it was analysed using enzymatic oxidation in the presence of glucose oxidase by ADVIA™ Chemistry Systems. The remaining 3.5 ml of blood was put into plain tube to let it clot. The serum was then analysed by the ADVIA™ Chemistry Systems using enzymatic method to measure TC and TG level. The cholesterol from non-HDL particles was released and eliminated for the measurement of HDL level. LDL levels was calculated by the Friedwald equation (Friedwald *et al.*, 1972).

Statistical analysis

Data were analysed using Stata version 8.0. Data were checked for data-entry error, explored and cleaned before analysis was done to check for completeness and accuracy of the data. Data were presented as mean and standard deviation or median and interquartile range depending on the data distribution. Categorical data were expressed as frequency and percentage. Small cells of categorical variables were combined as clinically meaningful if needed.

Simple linear regression was used to find the factors associated with HbA_{1c} levels in poorly controlled type 2 diabetic patients, followed by multiple linear regression. The model was fit with linearity, normality and equal variance assumptions were satisfied, but in view of influential effect of a few outliers, iteratively reweighted least square (IRLS) robust regression was used, from which the interpretation for regression coefficients with its 95% confidence interval (CI) and *p*-value were made. Level of significant was set at 0.05 with two-tailed fashion.

RESULTS

A total of 219 type 2 diabetic patients were recruited in this study. Eleven subjects were excluded because their

Table 1. Socio-demographic characteristics of 208 subjects

Characteristics	Frequency (%)		
	Male	Female	Total
Occupation			
Government	15 (17.9)	7 (5.6)	22 (10.6)
Private sector	3 (3.6)	3 (2.4)	6 (2.9)
Self-employed	27 (32.1)	24 (19.4)	51 (24.5)
Pensioner	27 (32.1)	3 (2.4)	30 (14.4)
Housewife	0 (0.0)	63 (50.8)	63 (30.3)
Others[a]	12 (14.3)	24 (19.4)	36 (17.3)
Educational level			
No formal education	5 (6.0)	20 (16.1)	25 (12.0)
Primary education	37 (44.0)	63 (50.8)	100 (48.1)
Secondary and tertiary education	42 (50.0)	41 (33.1)	83 (39.9)
Smoking status			
Non-smoker	23 (27.4)	118 (95.2)	141 (67.8)
Current smoker	32 (38.1)	0 (0.0)	32 (15.4)
Ex-smoker	29 (34.5)	6 (4.8)	35 (16.8)
Marital status			
Married	80 (95.2)	95 (76.6)	175 (84.1)
Others[b]	4 (4.8)	29 (23.4)	33 (15.9)
Family history of diabetes			
Yes	40 (47.6)	75 (60.5)	115 (55.3)
No	44 (52.4)	49 (39.5)	93 (44.7)
HC[c] with FMS[d]			
Yes	24 (28.6)	33 (26.6)	56 (26.9)
No	60 (71.4)	91 (73.4)	152 (73.1)

[a] Self-employed but currently not working anymore
[b] Either single, widowed or divorced
[c] HC = Health Clinic
[d] FMS = Family Medicine Specialist

HbA_{1c} levels turned out to be less than 6.5% and their characteristics did not differ from the rest of the group. The total number of subjects available for analysis was 208. The mean age of these subjects was 55.6 years old (SD=8.55) and the median duration of diabetes was 6 years (IQR=7). Their median monthly household income was RM500 (IQR = 485). Majority of the subjects were females (59.6%), married (84.1%) and had positive family history of diabetes (55.3%). All of our subjects were Malays. Other sociodemographic variables were shown in Table 1.

Table 2 showed the clinical characteristics of the subjects. Majority of them had poor FBG levels of more than 6.1 mmol/L (93.7%). The percentage of subjects with TC levels of more than 5.2 mmol/L was 75.0%, LDL levels of more than 2.6 mmol/L was 91.3%, HDL levels of less than 1.1 mmol/L was 31.3% and TG levels of more than 1.7 mmol/L was 49.0%. Seventy five percent of the subjects were obese with BMI of more than 23 and 67.8% of them had systolic and/or diastolic hypertension. Those with SBP of more than 130 were 58.7% and DBP of more than 80 were 38.9%.

Simple linear regression found significant association between HbA_{1c} levels and FBG, educational level, marital status and whether patients receiving their care in HC with FMS or not (data is not shown). The same factors were found to have significant association with HbA_{1c} levels in multiple linear regression. IRLS robust regression was used to remedy the influential effects of a few outliers found during model assessment (Table 3). High HbA_{1c} levels were associated with high FBG, having had no formal education, being married and receiving diabetic care in HC with Family Medicine Specialist (FMS).

With every one mmol/L increase in FBG levels, there was an increase of 0.236 unit (95% CI=0.189, 0.283) in HbA_{1c} levels. Those who had had primary education had 0.965 unit (95% CI=-1.550, -0.380) lower HbA_{1c} levels as compared to those with no formal education, and those who had had secondary or tertiary education had 0.625 unit (95% CI=-1.228, -0.021) lower HbA_{1c} levels as compared to those with no formal education. Being married was associated with 0.933 unit (95% CI=0.426, 1.440) higher HbA_{1c} levels as compared to others who were either widowed, divorced or single. Subjects receiving their diabetic care in HC with FMS had better HbA_{1c} levels as compared to those who received their diabetic care in HC without FMS with the difference in HbA_{1c} levels of 0.495 unit (95% CI=-0.913, -0.076).

DISCUSSION

The socio-demographic characteristics of the 208 subjects in this study were almost similar with the findings of two other studies done in Kelantan, even though the studies recruited all type 2 diabetic patients, regardless of their glycaemic control (Eid *et al.*, 2003, Suhaiza et al., 2004). High HbA_{1c} levels were found to be significantly associated with

Table 2. Clinical characteristics of 208 subjects

Characteristics	Mean (SD[a])		
	Male	Female	Total
HbA_{1c} (%)	10.21 (1.712)	10.14 (1.683)	10.17 (1.691)
Fasting blood glucose (mmol/L)	11.83 (3.662)	12.03 (4.159)	11.95 (3.958)
Total cholesterol (mmol/L)	5.78 (.952)	6.35 (1.248)	6.12 (1.170)
Triglycerides (mmol/L)	1.8 (1.1)*	1.7 (1.1)*	1.7 (1.0)*
HDL[b]-cholesterol (mmol/L)	1.126 (0.2027)	1.324 (0.2724)	1.244 (0.2646)
LDL[c]-cholesterol (mmol/L)	3.72 (0.860)	4.07 (1.099)	3.93 (1.021)
Body mass index (kg/m^2)	24.90 (3.511)	26.39 (4.000)	25.83 (3.919)
Systolic blood pressure (mmHg)	138.1 (20.13)	134.4 (20.11)	135.9 (20.15)
Diastolic blood pressure (mmHg)	77.7 (10.42)	78.9 (9.82)	78.4 (10.06)

* Median (Interquartile range)
[a] SD = standard deviation
[b] HDL = high-density lipoprotein
[c] LDL = low-density lipoprotein

Table 3. Factors associated with HbA_{1c} levels by Multiple Linear Regression*

	b coefficient (95% CI[a] of β)	*t* statistic (*df*[b])	*p*-value
Fasting blood glucose (mmol/L)	0.236 (0.189, 0.283)	9.94 (200)	< 0.001
Educational level			
No formal education	0.000		
Primary education	-0.965 (-1.550, -0.380)	-3.25 (200)	0.001
Secondary and tertiary education	-0.625 (-1.228, -0.021)	-2.04 (200)	0.042
Marital status			
Others	0.000		
Married	0.933 (0.426, 1.440)	3.63 (200)	< 0.001
HC with FMS			
No	0.000		
Yes	-0.495 (-0.913, -0.076)	-2.33 (200)	0.021

* IRLS robust regression (n=208), $R^2 = 0.353$
[a] CI = confidence interval
[b] *df* = degree of freedom

high FBG, having had no formal education, being married and receiving diabetic care in HC with Family Medicine Specialist (FMS) in this study.

Even though FBG is not exactly an associated factor for HbA_{1c} levels, but it was found to have highly significant association with the HbA_{1c} levels. This finding is similar with a few other studies which found highly significant correlation between FBG and HbA_{1c} levels (Schmitz *et al.*, 2000, Bonora *et al.*, 2002). HbA_{1c} levels is currently accepted as the recommended tools to monitor the glycaemic control in diabetic patients because it can measure the average control during the preceding two to three months (Goldstein *et al.*, 2004). However, the result of this study and supported by the few other studies gave a justification for the usage of FBG levels to monitor the glycaemic control in diabetic patients during clinic follow-up, especially in remote or rural areas where the HbA_{1c} testing might not be easily available.

Formal education was found to be significantly associated with better HbA_{1c} levels in this study. A study done in Pakistani Moslems with type 2 diabetes showed that illiterate women were more likely to have poorer glycaemic control and less likely to understand about the management of diabetes, thus they might find it more difficult to learn how to apply their knowledge to daily life (Hawthorne and Tomlinson, 1999). There is still unclear relationship between literacy and health, however, people with low literacy are more likely to report having poor health, using the emergency room and being admitted as inpatients. Patients illiteracy could be the underlying cause of non-compliance to medication, simply because they cannot read their drug prescription (Marcus, 2006).

Health literacy, defined as the skills needed to perform basic reading and numerical tasks required to function in the health care environment, might also play a role in the outcome of diabetes. It is more common among patients with low educational level, elderly and ethnic minorities (Ad Hoc Committee on Health Literacy, 1999). Patients with poor health literacy levels would have difficulty in doing simple and more difficult tasks, such as reading a simple prescription label, or more difficult instructions such as complex dosing schedules, physician recommendations, educational brochures, etc. (Schillinger *et al.*, 2002, Rothman *et al.*, 2004). A study found that diabetic patients with low health-literacy had significantly poorer knowledge about the treatment of diabetes (Rothman *et al.*, 2002). Another study found that inadequate health literacy was independently associated with worse glycaemic control (Schillinger *et al.*, 2002). Unfortunately, physicians rarely think about patients' health literacy. With current practice

environment which provide little time for information giving, the gap has risen between what patient actually understand and what health care providers think they know. Patients who do not understand health care providers instructions will not receive quality medical care (Ad Hoc Committee on Health Literacy, 1999).

Being married was also found to be a significant associated factor for HbA_{1c} levels in poorly controlled diabetic patients in this study, compared to others who were either single, widowed or divorced. A married female patient might just cook foods to accommodate her family, otherwise she might be in conflict with her maternal and domestic roles which emphasize others' needs over their own (Epple *et al.*, 2003). Otherwise, a married male patient might just eat what his wife cooked for the whole family. Therefore, it is strongly recommended that besides concentrating the diabetes education program on the diabetic patients themselves, involvement of the family members and addressing their issues in the education program is also needed. The education must provide information about the medical management of the disease and also related skills (Henessy *et al.*, 1999). Study by Epple *et al.* (2003) found that active family nutritional support was significantly associated with better control of TG, TC and HbA_{1c} levels.

Understanding of the management of diabetes is essential if any family members of diabetic patients are to be involved in diabetes-related care of the patients. Family members of diabetic patients were found to be more likely to be involved in diabetes-related care when the patients had physical impairment, if they were the spouse and when they had greater understanding of the management of diabetes (Henessy *et al.*, 1999). A focus group discussion found out that despite concern exhibited by family members about the patients' disease or condition, their lack of understanding about the disease and management might prompt them to provide poor health advice or informational support, example regarding what the patients can or cannot eat (Carter-Edwards *et al.*, 2004).

Subjects receiving their diabetic care in HC with FMS were found to have better HbA_{1c} levels as compared to those receiving their diabetic care in HC without FMS. It is well accepted that the best and ideal way to provide diabetes care is under the team setting, including regular services of specialist or physician and certified diabetes educators and nutritionists (Cobin, 2002). They would have greater knowledge about the disease, more focused in practice, being under a setting with good support systems, had better practice structure and recall systems to ensure patients visit and compliance. A study found that patients under the care of doctors who professed a special interest in diabetes, bigger and better equipped practices, practices with a diabetic miniclinic and patients with access to dietetic services had better glycaemic control (Pringle *et al.*, 1993).

In a study done in USA, even though no difference was seen in term of HbA_{1c} levels, but diabetic patients under endocrinologists care showed reduction in term of foot ulcer and infection, as compared to general practitioners (Greenfield *et al.*, 1995). Patients cared for by physicians in diabetes clinic has also been shown to receive better quality of diabetes care than did patients cared for by physicians in the general medical clinic in term of record of patients' self monitoring of blood glucose levels, foot examination, comprehensive eye examination, HbA_{1c} measurement and referral for diabetic education (Ho *et al.*, 1997). A cross-sectional analysis from the Pittsburgh Epidemiology of Diabetes Complication Study found that patients who received specialist care were significantly associated with lower HbA_{1c} levels (Zgibor *et al.*, 2000).

The benefits of subspecialty care in management of diabetic patients include better information, dedication, commitment, focus and attention to the spectrum and complexities of life for these patients. Specialists may also have more experience and comfort with OHA and thus be more aggressive with their use when glycaemic control is inadequate (Cobin, 2002, Shah *et al.*, 2005). Specialists were also thought to demonstrate less "clinical inertia", defined as the recognition of a problem with a patient's management but fail to act (Shah *et al.*, 2005). Clinical inertia could be the cause of inadequate glycaemic control in diabetic patients because their health care providers failed to intensify their management accordingly. Specialists were found to be more aggressive with insulin initiation than primary care physicians, which reflects specialists' greater familiarity with starting insulin treatment and this may contribute to the lower HbA_{1c} levels seen with specialist care. However, clinical inertia observed in diabetes care practice could also be due to valid clinical or social circumstances, such as significant or frequent hypoglycaemia despite high levels of HbA_{1c}, comorbidities or other patients'factor (Shah *et al.*, 2005).

R^2 value for multiple linear regression in this study is 0.353, meaning that only 35.3% of the variance in HbA_{1c} levels in the sample was explained by the four significant variables observed. There were many other factors which could be associated with HbA_{1c} levels in poorly controlled type 2 diabetics which were not studied here, and health care providers' factor may also play a significant role, which is out of the scope of this study. The cross-sectional nature of this study however prevent any causal relationship to be made from any significantly associated variables found.

In conclusion, higher FBG levels and being married were significantly associated with higher HbA_{1c} levels, while formal education and receiving diabetes care in HC with FMS were associated with better HbA_{1c} levels in poorly controlled type 2 diabetics in Kelantan, North-East Malaysia.

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