**TITLE PAGE**

**Title:** Effect of Hypertension and Dyslipidemia on glycemic control among Type 2 Diabetes patients in Thailand

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**Abstract**

**Background:** Type 2 diabetes is a common and serious condition associated with reduced life expectancy and considerable morbidity. Hypertension and dyslipidaemia are common co-morbidities in patients with type 2 diabetes which can lead to micro-vascular and macro-vascular complications. Strict control of blood glucose, blood pressure and cholesterol could minimize the complications of diabetes (DM). Good glycemic control is essential in preventing the complication of diabetes. Little is known about the effect of co-morbidities of hypertension and dyslipidemia on glycemic control in Thailand.

**Objective:** To determine effect of hypertension and dyslipidemia on glycemic control in Type 2 Diabetes patients in Thailand.

**Methods:** This study was a hospital based cross-sectional study and also part of the an assessment on quality of care among patients diagnosed with Type 2 Diabetes and/or Hypertension visiting Hospitals in care of Ministry of Public Health and Bangkok Metropolitan Administration in Thailand, 2010-2012. The data were collected from the medical records of 79,543 type 2 diabetes patients. Hba1c level was the main outcome of the study and the patients were diagnosed as good glycemic control by HbA1c level less than 7%. The type 2 diabetes patients were also categorized into 4 groups according to presence of co-morbidities; diabetes alone, diabetes with hypertension, diabetes with dyslipidemia and diabetes with both co-morbidities in order to assess the glycemic control in each group. Data analysis was done by using multiple logistic regression.

**Results**: In this study, 34.4% (95% CI: 34.0 -34.8) of DM patients were found to have good glycemic control (Hba1c <7%). Among them, 42.2% (95% CI: 40.5-43.9) of patients from DM alone group, 43.2% (95% CI: 41.8-44.6) of patients from DM with hypertension group, 32.5% (95% CI: 32.8 -33.8) of patients from DM with dyslipidemia group and 33.3% (95% CI: 32.8 -33.8) of patients from DM with both co-morbidities group were getting control of HbA1c level. Bivariate logistic regression revealed that patients with dyslipidemia had 1.5 times the odds of getting uncontrolled of Hba1c level compared to patients with DM alone (OR=1.5, 95% CI:1.4-1.6). Elevated Triglyceride is significantly associated with poor glycemic control (OR=1.48, 95% CI:1.43-1.54). However hypertension was not significantly associated with HbA1c level in this study. In multiple logistic regression, DM patients with both comorbidities of hypertension and dyslipidemia had 1.5 times the odds of getting uncontrolled HbA1c level compared to DM alone patients (OR: 1.47, 95% CI:1.34-1.62).

**Conclusion:** According to the results, dyslipidemia was the main predictor of determining glycemic control by Hba1c level in type 2 diabetes patients.

**Key words:** Type 2 diabetes mellitus, hypertension, dyslipidemia**.** HbA1c

**INTRODUCTION**

 Diabetes is a lifelong chronic disease characterized by elevated blood sugar level. There are two main types of diabetes, referred to as type 1 and type 2. Type 2 diabetes results from insulin resistance i.e the body’s cells don't respond to insulin or the body doesn't produce enough insulin from the pancreas (1). Diabetes is a global endemic with rapidly increasing prevalence in both developing and developed countries. It is projected that the number of individuals with diabetes will rise from an estimated 385 million in 2010 to 439 million in 2030(2). Majority of them are from developing world (3).In Thailand NCDs are estimated account for 71% of all deaths in which diabetes was contributed 6%. According to 2010 WHO data base, about 7.3% of the individuals had diabetes in Thailand(4). Hypertension, overweight and dyslipidemia are often accompanied with Type 2 diabetes that affect morbidity and mortality (5)(6).

 Good glycemic control is essential in preventing diabetic complications such as cardiovascular diseases, diabetic nephropathy and retinopathy etc.(6). The level of glycosylated hemoglobin (HbA1c) provides a useful measure of the glycemic control in diabetes patients (7)(8). Each 1% reduction in HbA1c was associated with a 37% decrease in risk for microvascular complications and a 21% decrease in the risk of diabetic related death(9). Studies in other countries have demonstrated that there were controversies in association between hypertension, age, body mass index (BMI) and HbA1c level(10)(11)(12)(13). Some previous studies revealed that Triglyceride and LDL were positively correlated with HbA1c (14)(15)(16)(17). Many literature have documented that the greater the duration of diabetes the poorer was the glycemic control(11)(18).

 Diabetes has been considered as a global concern to reduce morbidity and mortality. Although many studies on DM have been undertaken worldwide, little is known about the effect of Hypertension and Dyslipidaemia on HbA1c level in Thai population with Nationally representative sample. The aim of this study was to determine effect of hypertension and dyslipidemia on glycemic control in Type 2 Diabetes patients by HbA1c level.

**MATERIALS AND METHODS**

***Study design***

This study was a hospital based cross-sectional study and utilized the data that is part of the study: “An assessment on quality of care among patients diagnosed with Type 2 Diabetes and Hypertension visiting Ministry of Public Health and Bangkok Metropolitan Administration Hospitals in Thailand (Thailand DM/HT)” which was conducted from 2010 to 2012. Nationally representative sample of 174,578 patients with diabetes and/or hypertension were randomly selected from 600 hospitals across Thailand. The sample was selected based on the probability proportional to size of the patients for each hospital. Data collection involved medical record review conducted by well trained research nurses.

***Study outcome*** The primary outcome of this study was the proportion of DM patients who were getting control of diabetes by HbA1c level less than 7% according to absence or presence of comorbidities and the effect of co-morbidities (hypertension and dyslipidemia) on the HbA1C level was the secondary outcome. The patients were considered to have dyslipidemia if there was at least one abnormal level in the lipid profile (LDL >100 mg/dl, HDL <40 mg/dl, and triglycerides >150 mg/dl) and have hypertension if the blood pressure was more than 130/80 mmHg(19).

***Statistical analysis***

* *Methods for describing baseline characteristics of the sample:* Demographic characteristics of the participants were described using frequency and percentage for categorical data and mean and standard deviation for continuous data.
* *Methods for answering the research question(s):* The proportion of the patients with HbA1c level<7% was calculated among four different category groups; diabetes alone, diabetes with hypertension, diabetes with dyslipidemia and diabetes with both hypertension and dyslipidaemia. The 95% confidence interval (CI) was also computed based on normal approximation to binomial distribution. To determine the effect of hypertension and dyslipidemia on HbA1c level, odds ratios (ORs) and their 95% confidence intervals (95%CIs) were estimated using multiple logistic regression and adjusted for demographic characteristics and those showing the bivariate relationship with the outcome variable such as age, gender, BMI and duration of diabetes etc.
* *Software, level of significant, and ethics*: the data were analyzed by Stata software version 12.0 (Stata Corp, College Station, TX). All test statistics were two-sided and a p-value of less than 0.05 was considered statistical significant. This project was approved by ethical board of Khon Kaen University.

**RESULTS**

A total of 3.373,089 type 2 DM and/or hypertension patients were visited the hospitals in care of Ministry of Public Health and Bangkok Metropolitan Administration in Thailand during 2010 to 2012. From 174,578 randomly selected patients, 95,035 were excluded for being having hypertension alone, hence 79,543 type 2 DM patients were included in the analysis (Fig.1)

Total number patients visiting 600 hospitals across the Thailand

(N=6,277,543)

Type 2 DM & HT patients

(N=174,578)

 Exclude HT patients

 (95,035)

 Type 2 DM patients

( N-79,543)

 Missing (20,800)

Sample size of the study

 (N=58,743)

(58,743)

**Fig. 1.** The inclusion flow chart

***Characteristics of patients***

 Among 79,543 Type 2 DM patients, majority of them (89.9%) were female, with mean age of (59.3+10.7) years ranged from 20 to 98 years. They were mainly agricultural workers (42,8%) followed by housekeeper (23.3%). Mean duration of diabetes was (7.17+4.64) and only one third, 34.46% of the patients had good glycemic control. More than half (61.47%) of the patients had hypertension and majority of the patients (85.69%) had comorbidity of dyslipidaemia.

**Table 1.** Characteristics of type 2 diabetic patients.

|  |  |  |
| --- | --- | --- |
| Characteristics | No. | Percentage |
| Age  |  |  |
| Mean ± standard deviation |  |  59.3+10.7 |
| Median (Min:Max)  |  |  60(20,98) |
|  |  |  |
| Gender |  |  |
| Male  | 17,529 |  29.95 |
| Female  | 41,145 |  70.05 |
|  Total | 58,737 | 100.0 |
|  |  |  |
| Occupation |  |  |
|  Farmer or farm worker  Government employee Trader or Merchant  State Enterprise Employee Private corporation officer  Laborer (include day labors) Student  Housekeeper/ unemployed person Self‐Employed/Own Business  Monk/nun/priest Other Total **BMI(Kg/m2)** < 25 25 to 30 >30 Total Mean ± standard deviation Median (Min:Max) **Duration of diabetes** **< 7 years** **> 7 years**TotalMean ± standard deviation Median (Min:Max) **HbA1c level** < 7% > 7% Total Mean ± standard deviation Median (Min:Max) **Hypertension** Yes No Total**Dyslipidaemia** Yes No Total**TG level** < 150mg/dl > 150mg/dl  Total Mean ± standard deviation Median (Min:Max) **LDL level** < 100mg/dl > 100mg/dl  Total Mean ± standard deviation Median (Min:Max) **HDL level** < 40mg/dl > 40mg/dl  Total Mean ± standard deviation Median (Min:Max)  | 24,0742,5544,4352374439,9751713,6171802231,77457,51926,66619,9257,64754,23824,74415,37040,114 20,24238,501587,4336,02822,58558,61347,1697,87455,043   26,54424,19750,74122,59829,60752,205 16,73031,61148,341 | 41.854.427.710.410.7717.340.0323.670.310.393.09100.049.1636.7414.10100.025.5+ 4.4425.1(8,98,91.96) 61.6636.32100.07.17+4.646(0,55) 34.4665.54100.008+1.91.6(1,17)61.4738.53100.0  85.69 14.31100.052.3147.69100.0161.81+73.5146(40,400)43.2956.71 100.0110.69+36.9106(40,400)34.6165.39100.045.29+12.244(20,100) |

***Proportion of patients who are getting control with HbA1c level less than 7%***

Out of 58,743 patients, 34.4% (95% CI: 34.0 -34.8) were getting control of HbA1c level. Among them 42.2% (95% CI: 40.5-43.9) of patients from patients with diabetes alone group, 43.2% (95% CI: 41.8-44.6) of patients from DM with hypertension group, 32.5% (95% CI: 32.8 -33.8) of patients from DM with dyslipidemia group and 33.3% (95% CI: 32.8 -33.8) of patients from DM with hypertension and dyslipidemia group were getting glycemic control (i.e HbA1c level less than 7%)***.***

***Factors associated with Hba1c level***

In type 2 diabetes patients, dyslipidemia is significantly associated withHbA1c level,i.e DM patients with dyslipidemia were 1.5 times the odds of getting uncontrolled HbA1c level compared to those patients without dyslipidemia (OR=1.54, 95% CI:1.39-1.69). High level of triglyceride was a strong risk factor for poor glycemic control (OR=1.51, 95% CI: 1.44-1.58). Elevated LDL level is significantly associated with failure to achieve the targeted HbA1c level(OR=1.29, 95% CI: 1.24-1.36).

**Table. 2.** Crude odds ratios (OR) and 95% CI for getting poor glycemic control by using logistic regression

 Analysis

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable** | **Total** | **%****Hba1c>7%** | **Crude OR** | **95%CI** | **p-value** |
| Comorbidities DM aloneDM with HTDM with DyslipidaemiaDM with both |  1,8432,65212,15919,380 | 57.7656.8167.4666.70 |  10.961.521.46 |  |  | <0.001 |
|  0.89-1.05 1.40-1.63 1.36-1.58 |
| **Gender**MaleFemale | 10,88527,614 | 61,8767.11 | 11.25 |   1.21-1.30 | <0.001 |
|  |
|  |
| **Age** < 60 years**≥** 60 years | 20,42718,009 | 71.6459.75 |  |  |  | <0.001 |
| 10.59 |  |  |  |
| 0.57-0.61. |  |
| **Triglyceride**<150 mg/dl>150 mg/dl |  | 60.8869.79 | 11.48 |  |  | <0.001 |
| 16,16016,888 |  |  |  |
|  1.43-1.54 |  |
| **HDL** >40 mg/dl <40 mg/dl | 20,54011.309 | 64,9867.60 | 11.12 |  |  | <0.001 |
|  |  |  |
|  1.08-1.17 |  |
| **LDL** <100 mg/dl >100mg/dl | 14,07720,192 | 62.2968.20 | 11.29 |  1.25-1.35 | <0.001 |
| **BMI(Kg/m2)** < 251. to 30

 >30 | 17,15813,4015,252 | 64.3467.2668.68 | 11.141.22 |  1.09-1.18 1.15-1.28 | <0.001 |
| **Duration of DM** **< 7 years** **> 7 years** | 15,52110,973 | 62.7371.39 | 11.48 |  | 1.42-1.55 | <0.001 |

**Table. 3.**  Odds ratios (ORs) for getting poor glycemic control and their 95% confidence intervals for each

 factor adjusted for all other factors presented in the table using multiple logistic regression.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Variable** | **Total** | **%****Hba1c >7%**  | **Crude OR** | **Adjusted OR** | **95%CI** | **p-value** |
| **Comorbidities** DM aloneDM with HTDM with DyslipidaemiaDM with both | 1,8432,65212,15919,380 | 57.7656.8167.4666.70 |  10.961.521.46 | 10.931.541.47 | 0.83-1.051.39-1.691.34-1.62 |  <0.001 |
|  |
|  |
|  |
| **Gendere**MaleFemale | 10,88527,614 | 61,8767.11 | 11.25 | 11.2 |  1.15-1.26 | <0.001 |
| **Age**<60 years>60 years | 20,42718,009 | 71.6459.75 | 10.59 | 10.58 |  0.56-0.61 | <0.001 |
| **Triglyceride**<150 mg/dl>150 mg/dl | 16,16016,888 | 60.8869.79 | 11.40 | 11.51 |  1.44-1.58 | <0.001 |
| **HDL**>40 mg/dl <40 mg/dl | 20,54011.309 | 62.2967.60 | 11.12 | 11.14 |  1.08-1.20 | <0.001 |
| **LDL**<100 mg/dl>100 mg/dl | 14,07720,192 | 60.8868.20 | 11.29 | 11.29 |  1,24-1.36 | <0.001 |
| **BMI(Kg/m2)**<25 25 - 30 >30 | 17,15813,4015,252 | 64.3467.2668.68 | 11.141.22 | 11.111.10 |  1.06-1.16 1.03-1.18 | <0.001 |
| **Duration of Diabetes**<7 years>7 years | 15,52110,973 | 62.7371.39 | 11.48 | 11.61 |  1.54-1.69 | .<0.001 |

***The effect of hypertension and dyslipidemia on determining HbA1c level of type 2 diabetes patients***

 The dyslipidemia, comorbidity of diabetes, was the main predictor of determining the HbA1C level, i.e. DM patients with dyslipidemia comorbidity were 1.5 times the odds of getting poor glycemic control than those with diabetes alone (OR = 1.54; 95% CI: 1.39-1.69; *p* < 0.001). However hypertension is not significantly associated with glycemic control in this study (OR = 0.93; 95% CI: 0.83-1.05; *p* < 0.227). DM patients with both comorbidities have 47% chance of getting poor glycemic control than DM alone patients (OR = 1.47; 95% CI: 1.34-1.62; *p* < 0.001).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Odds ratio**  |  **95%CI** |  **p-value** |
|  |  |  |  |  |
| DM with HT |  |  0,93 |  0.83-1.05 |  <0.227 |
| DM with Dyslipidaemia  |  1.54 |  1.36-1.69 |  <0.001 |
| DM with HT and Dyslipidaemia1.11 0.9 0.8 |  1.7 1.6 1.51.41.31.2.5 |  1.47α |  1.34-1.62 |  <0.001 |
|  |  |  |  |  |

**Fig. 2** The effect of hypertension and dyslipidaemia on determining Hba1C level, presented as odds ratio adjusted for age, gender, BMI and duration of diabetes using multiple logistic regression

**DISCUSSIONS**

According to the results, out of total 58,743 patients, only 34.46 % of the type 2 DM patients had good glycemic control, however majority of them did not achieve the target goal of HbA1c level <7%. Achievement of glycemic control varied widely on the life style, type of medication, patients’ education as well as data collection method. Attaining the targeted goal of HbA1c level in some research were 56.1% in Jordan(18), 51% in Canada(20), 55.7% in USA(21) and 31.78% in China(22) respectively. Based on the data from Thai Diabetes Registry Project in 2006, only 37.7% of their participants were getting control of HbA1c <7%(23). This finding was better than our study. Hence it was essential to pay greater attention on achieving good glycemic control of Type 2 DM patients in Thailand. The majority of the patients achieving the targeted goal of HbA1c level were old age group of more than 60 years which was not different from the study conducted in Malaysia(24) . This was because the mature patients perceived themselves to have better glycemic control over their lives or may be more motivated to take care of their health than younger age group. Poor glycemic control was associated with longer duration of diabetes which was not different from the studiesken in Jordan and Saudi Arabia(11)(18). This may be due to the progressive destruction of beta cells of the pancreas(25).

The overall prevalence of hypertension, dyslipidemia and the obesity (BMI>30) of this cohort were 61.5%, 85.7% and 14.1 % respectively. Only 33% of the patients from DM with both comorbidities had good glycemic control. Poor glycemic control could be due to the presence of comorbidities of hypertension and dyslipidemia . Both hypertension and dyslipidemia in diabetes patient can predispose to cardiovascular disease (CVD). Achieving the targeted goal of HbA1c level less than 7% is essential for preventing diabetic complications (5). This study revealed that there was no association between hypertension and HbA1c level which was not consistent with other studies (10). This could be the limitation of this study not being considered by antihypertensive use. Elevated LDL level (56.7%) and raised TG level (47.75%) were the prevalent pattern of dyslipidaemia in this study. Dyslipidemia, due to elevated TG and LDL, was significantly associated with poor glycaemic control in this study population. It was consistent with the studies conducted in other countries(14)(15)(16)(17).

In conclusion, majority of the type 2 DM patients in Thailand had poor glyeacmic control. More than half of the patients have hypertension and almost all the patients were coexisting with dyslipidemia. Of particular interest there was no association between hypertension and HbA1c level. However DM patients with dyslipidemia had 50% more chance of getting poor glycemic control than patients with DM alone. Therefore dyslipidemia was the main predictor of determining glycemic control by HbA1c level.

***Strength of the study***

This study consisted of Nationally representative sample of larger sample size.

***Limitation of the study***

This cross- sectional study was limited to data available in hospital and not obtained prospectively. Comparisons cannot be made with community-based studies. Insufficient data and missing values were unavoidable because of the secondary data.

The design of study was cross-sectional study that showed the association of each factor might not be able to determine the cause and effect of each associated factor.

***Conclusions***

According to the results, dyslipidaemia was the main predictor of determining glycemic control by Hba1c level. Reduction of the modifiable risk factors such as BMI, hypertension and dyslipidemia and good glycemic control through public health efforts may help to reduce the risk of DM and its chronic complications.

***Recommendations***

* Effective control of Dyslipidemia in Type 2 DM patients is urgently needed to prevent or reduce the risk of developing the complications.
* An educational program that emphasizes lifestyle modification with importance of adherence to

treatment regimen would be of great benefit in glycemic control.

* Population based and prospective study should be conducted in the future.

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