**TITLE PAGE**

**Title:** Hypertension and Dyslipidaemia on determining HbA1c level among Type 2 Diabetes patients

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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. Strict control of blood glucose, blood pressure and cholesterol could minimize the complications of DM. Little is known about the effect of co-morbidities of hypertension and dyslipidaemia on Hba1c level in Thailand.

**Objective:** To determine effect of hypertension and dyslipidaemia on Hba1c level in Type 2 Diabetes patients

**Methods:** The study used the data collected from the medical records of type 2 diabetes patients visiting Hospitals in care of Ministry of Public Health and Bangkok Metropolitan Administration in Thailand. Patients were diagnosed as controlled by HbA1c level less than 7% and also categorized into 4 groups according to presence of co-morbidities; diabetes alone, diabetes with hypertension, diabetes with dyslipidaemia and diabetes with both co-morbidities.

Results: In this study, 34.52% (95% CI: 34.17 -34.94) of DM patients were found to have Hba1c <7% (controlled). Among them, 6.98% (95% CI: 6.63 -7.34) of patients were from DM alone group, 14.41% (95% CI: 13.9-14.9) of patients were from DM with hypertension group, 29.61% (95% CI: 28.9 -30.3) of patients were from DM with dyslipidaemia group and 49% (95% CI: 48.3 -49.7) of patients were from DM with both co-morbidities group respectively. Bivariate logistic regression revealed that hypertension was not significantly associated with Hba1c level. In multiple logistic regression, DM patients without dyslipidaemia had 1.4 times the odds of getting HbA1c control compared to DM with dyslipidaemia (OR=1.4, 95% CI:1.44=1.59).

**Conclusion:** According to the results, dyslipidaemia was the strong predictor of determining Hba1c level in type 2 diabetes patients.

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

**INTRODUCTION**

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(1). Majority of them are from developing world (2). According to 2010 WHO data base, 7.3% of the individuals had diabetes in Thailand. Hypertension, overweight and dyslipidemia are often accompanied with Type 2 diabetes that affect morbidity and mortality (3)(4).

Good glycemic control is essential in preventing diabetic complications such as cardiovascular diseases, diabetic nephropathy and retinopathy etc.(4). The level of glycosylated hemoglobin (HbA1c) provides a useful measure of the glycemic control of diabetes patients (5)(6). Studies in other countries revealed that there was a positive correlation between Triglyceride level and HbA1c (7)(8). HbA1c was also associated with body mass index and hypertension(9).

Diabetes has been considered as a global concern to reduce morbidity and mortality. Although many studies on DM have 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 dyslipidaemia on getting control of Type 2 Diabetes patients by HbA1c level.

**MATERIALS AND METHODS**

***Study design***

The population based multiple cross-sectional study was conducted by using the data collected from the medical records of type 2 diabetes patients visiting Hospitals in care of Ministry of Public Health and Bangkok Metropolitan Administration in Thailand from 2010 to 2012. This study involved 174578 patients from 600 hospitals across the country.

***Study outcome***

The primary outcome of this study was how many patients were getting control of diabetes by HbA1c level less than 7% and the effect of co-morbidities (hypertension and dyslipidaemia) on the HbA1C level were the secondary outcome. The patients were considered to have dyslipidaemia if there was at least one abnormal level in the lipid profile (LDL >100 mg/dl, HDL <50 mg/dl, and triglycerides >150 mg/dl) and have hypertension if the blood pressure was more than 130/80 mmHg(10).

***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 dyslipidaemia 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 dyslipidaemia 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 univariate relationship with the outcome variable such as age, gender, co-morbidities etc.
* *Software, level of significant, and ethics*: the data were analyzed by Stata software version 12.0 (StataCorp, 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 ????

**RESULTS**

A total of 174578 patients visiting the hospitals in care of Ministry of Public Health and Bangkok Metropolitan Administration in Thailand during 2010 t0 2011 were the population of this study.(Fig.1)

Type 2 DM patients visiting the hospitals across the Thailand (Yearly)

2012, N=xxxx

2011, N=xxxx

Study population

N=174578

2010, N=xxxx

**Fig. 1.** The flow chart for study population

***Demographic Characteristics***

Among 174578 Type 2 DM patients, majority of them (xx.x%) were female, with mean age of (xx.xx+x.x) years ranged from xx to xx. They were mainly agricultural workers (xx.x%) followed by housekeeper (xx.x%) and majority (xx.x%) were Buddhists.

**Table 1.** Demographic characteristics of the participants.

|  |  |  |
| --- | --- | --- |
| Characteristics | No. | Percentage |
| Age ( completed years) | xx | xx.x |
| 20 - 29 | xx | xx.x |
| 30 – 39 | xx | xx.x |
| 40 – 49 | xx | xx.x |
| 50 – 54 | xx | xx.x |
| 60 or greater | xx |  |
| Mean ± standard deviation | xx.x± x.x |  |
| Range (Min:Max) | xx.x - xx.x |  |
|  |  |  |
| Gender |  |  |
| Male | xx | xx.x |
| Female | xx | xx.x |
|  |  |  |
| 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  Retired Government employee  Other | xx  xx  xx  xx  xx  xx  xx  xx  xx  xx  xx  xx | xx.x  xx.x  xx.x  xx.x  xx.x  xx.x  xx.x  xx.x  xx.x  xx.x  xx.x  xx.x |
| Religion |  |  |
| Buddhist | xx | xx.x |
| Islam | xx | xx.x |
| Christian | xx | xx.x |
| Others | xx | xx.x |

***Proportion of patients who are getting control with Hba1c level less than 7%***

Out of 174578 patients, xx.x% (95% CI: xx.x-xx.x) were getting control of Hba1c level i.e less than 7%. Among them xx.x% (95% CI: xx.x-xx.x) were from patients with diabetes alone group, xx.x% (95% CI: xx.x-xx.x) were from DM with hypertension group, xx.x% (95% CI: xx.x-xx.x) were from DM with dyslipidaemia group and xx.x% (95% CI: xx.x-xx.x) were from DM with hypertension and dyslipidaemia group,

**Table 2**. Proportion of patients who are getting control of Hba1c level less than 7% and their 95% confidence intervals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Hba1C level | DM alone | DM with HT | DM with  Dyslipidaemia | DM with HT and  Dyslipidaemia | Total  **(n=xx,xxx)** |
| < 7% | xx.x  (xx.x-xx.x) | xx.x  (xx.x-xx.x) | xx.x  (xx.x-xx.x) | xx.x  (xx.x-xx.x) | xx.x  (xx.x-xx.x) |
| ≥ 7% | xx.x  (xx.x-xx.x) | xx.x  (xx.x-xx.x) | xx.x  (xx.x-xx.x) | xx.x  (xx.x-xx.x) | xx.x  (xx.x-xx.x) |

***Factors associated with Hba1c level***

In type 2 diabetes patients, dyslipidaemia is significantly associated withHba1c level, DM patients without dyslipidaemia were xx times the odds of getting Hba1c level control compared to those patients with dyslipidaemia (OR = x.xx; 95%CI: x.xx –x.xx; *p* < 0.xxx).

**Table. 3.** Crude and adjusted Odds ratios with 95% CI for getting control on HbA1c by doing multiple

logistic regression analysis

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Factors | Crude OR | Adjusted OR | 95% CI | P- value |
| Age | x.xx | x.xx | x.xx – x.xx | 0.xxx |
| Gender | x.xx | x.xx | x.xx – x.xx | 0.xxx |
| Duration of DM | x.xx | x.xx | x.xx – x.xx | 0.xxx |
| Type of clinic | x.xx | x.xx | x.xx – x.xx | 0.xxx |
| DM with HT | x.xx | x.xx | x.xx – x.xx | 0.xxx |
| DM with Dyslipidaemia | x.xx | x.xx | x.xx – x.xx | 0.xxx |
| DM with both HT and Dyslipidaemia | x.xx | x.xx | x.xx – x.xx | 0.xxx |

***The effect of hypertension and dyslipidaemia on determining Hba1c level of type 2 diabetes patients***

The dyslipidaemia, comorbidity of diabetes, was the strong predictor of determining the Hba1C level, i.e. DM patients in the absence of comorbidities were xx times the odds of getting Hba1C control than those with comorbity of dyslipidaemia (OR = x.xx; 95%CI: x.xx –x.xx; *p* < 0.xxx).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Odds ratio** | **95%CI** | **p-value** |
| DM alone |  | x.xx | x.xx – x.xx | 0.xxx |
| DM with HT |  | x.xx | x.xx – x.xx | 0.xxx |
| DM with Dyslipidaemia | | x.xx | x.xx – x.xx | 0.xxx |
| DM with HT and Dyslipidaemia |  | x.xx  5  4  α  1  0.50  2  0 | x.xx – x.xx | 0.xxx |
|  | 3 |  |  |  |

**Fig. 1** The effect of hypertension and dyslipidaemia on determining Hba1C level, presented as odds ratio adjusted for age, gender, duration of diabetes, type of clinic, using multiple logistic regression

**DISCUSSIONS**

***Explaining the findings***

<copy narrative parts of the Results followed by explaining each important findings in turn , 5-10 references needed here in this section where about half of them are the same as the one cited in the Introduction section of the manuscript>

***Strength of the study***

<to be written>

***Limitation of the study***

* *Can selection bias distort the findings?*
* *Can information bias distort the findings?*
* *Can confounding bias distort the findings?*

***Conclusions***

(copy from the Conclusion section of the abstract then add some)

***Recommendations***

<to be written>

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