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### Comparison of Low Density Lipoprotein Cholesterol Concentrations by Direct Measurement and Friedewald Formula in Diabetic Patients with and without Hemoglobin E Disorders

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#### Abstract

**Background:** Low density lipoprotein cholesterol (LDL) levels were significantly lower in diabetic patients with homozygous hemoglobin E (HbEE) measured by a homogeneous assay.

**Objective:** Comparison of direct measurement of LDL (dLDL) determined by a homogeneous assay and calculated LDL (cLDL) determined by the Friedewald formula in diabetic patients with and without hemoglobin E disorders.

**Material and Method:** The hemoglobin E (HbE) screening test and hemoglobin (Hb) typing were conducted in diabetic patients at Surin Hospital. In 2,973 cases with triglyceride (TG) levels under 400 mg/dL, classification was determined into three groups, negative screening (NS), HbE trait (HbEA), and HbEE. The measurements of total cholesterol (TC) and TG were performed using enzymatic methods. The direct measurements of high density lipoprotein cholesterol (HDL) and LDL were performed using homogeneous methods.

**Results:** The prevalence of HbEE and HbEA were 7.6% and 35.7% respectively. The means of TG, CHOL, dLDL, cLDL, and non-HDL cholesterol (non-HDL-C) were significantly lower in HbEE ( $p = 0.009$ ,  $p < 0.001$ ,  $p < 0.001$ ,  $p < 0.001$ , and  $p < 0.001$  respectively). The mean of cLDL in each group was significantly lower than the mean of dLDL ( $p < 0.001$  at all). By the Passing-Bablok regression, the interception with 95% confidence interval (95% CI) of NS, HbEA, and HbEE were 4.322 (3.082 to 5.485), 6.625 (5.094 to 7.981), and 6.60 (3.347 to 10.356) respectively. The slope with 95% CI were 1.017 (1.007 to 1.027), 1.002 (0.991 to 1.016), and 1.0 (0.963 to 1.033) respectively. Using the Bland-Altman method, the mean with standard deviation of the difference between dLDL and cLDL in NS, HbEA, and HbEE were 6.758 (7.856) mg/dL, 7.350 (8.212) mg/dL, and 7.225 (7.129) mg/dL respectively. The 95% limits of agreement between the dLDL and cLDL in NS, HbEA, and HbEE were -8.640 to 22.156 mg/dL, -8.746 to 23.446 mg/dL, and -6.748 to 21.197 mg/dL respectively. The statistically significant difference of having more patients with cLDL <100 mg/dL than dLDL <100 mg/dL in each group were observed in most of the subgroups of TG levels at 100 mg/dL to <200 mg/dL and higher. HbEE had more patients of dLDL <100 mg/dL and cLDL <100 mg/dL than NS. The adjusted odds ratio and 95% CI were 1.383 (1.022 to 1.871) with  $p = 0.036$  and 1.838 (1.375 to 2.456) with  $p < 0.001$  respectively.

**Conclusion:** The direct homogeneous method showed a higher LDL concentration than the Friedewald formula indicated in diabetes and diabetes with HbE disorders. The percentage of higher LDL levels by direct method than Friedewald formula significantly increased along the subgroups of higher TG levels. The dissociation occurred at TG levels of 100 mg/dL and higher. Systematic biases between both methods were found in all groups but the proportional difference between both methods was only observed in diabetes without HbE disorders.

**Keywords:** Low density lipoprotein cholesterol, LDL, Direct measurement of LDL, Friedewald formula, Hemoglobin E disorders, HbEE, HbE trait, Diabetes mellitus, DM, Surin Hospital

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