Utilization of Calculated Low Density Lipoprotein Cholesterol and Measured Low Density Lipoprotein Cholesterol in Siriraj Hospital

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A study to determine the utilization of calculated low density lipoprotein (c-LDL) cholesterol and measured low density lipoprotein (m-LDL) cholesterol was conducted. The test results of total cholesterol, triglyceride, HDL-cholesterol and m-LDL-cholesterol from the same individuals aged ≥ 18 years who had the tests done at the Department of Clinical Pathology, Faculty of Medicine Siriraj Hospital during January to December 2004 were retrieved. The c-LDL-cholesterol level was computed using Friedewald formula. There were two data sets i.e. the m-LDL-cholesterol cut-off level derivation data set (784 subjects) and the m-LDL-cholesterol cut-off level validation data set (800 subjects). The study results revealed: 1) 2.6% of the subjects had blood triglyceride > 400 mg/dl hence c-LDL-cholesterol could not be computed, 2) the correlation between c-LDL-cholesterol levels and m-LDL-cholesterol levels from both data sets was very good (r > 0.95, p < 0.001), 3) the m-LDL-cholesterol levels were usually higher than c-LDL-cholesterol levels, 4) the m-LDL-cholesterol cut-off level derivation data set showed that m-LDL-cholesterol < 87, > 143, > 188, > 233 and > 254 mg/dl were highly correlated with c-LDL-cholesterol < 100, ≥ 100, ≥ 130, ≥ 160 and ≥ 190 mg/dl respectively, 5) an application of m-LDL-cholesterol cut-off levels derived from the m-LDL-cholesterol cut-off level derivation data set to the m-LDL-cholesterol cut-off level validation data set showed that m-LDL-cholesterol < 87, > 143, > 188, > 233 and > 254 mg/dl had accuracy in predicting c-LDL-cholesterol < 100, ≥ 100, ≥ 130, ≥ 160 and ≥ 190 mg/dl of 100%, 99.7%, 100%, 100% and 100% respectively, 6) the use of m-LDL-cholesterol levels as a guide for initiating lipid-lowering agents based on cut-off values of c-LDL-cholesterol levels led to an overuse of lipid-lowering agents in 3.6% to 42.9% of the patients and 7) Nomogram for transforming m-LDL-cholesterol to c-LDL-cholesterol was developed as well as a formula for transforming m-LDL-cholesterol to c-LDL-cholesterol (c-LDL-cholesterol = 0.89 ◊ m-LDL-cholesterol). Therefore, m-LDL-cholesterol assay has a very limited use in managing individuals with suspected or known dyslipidemia. The use of m-LDL-cholesterol level as a guide for management of abnormal LDL-cholesterol conditions leads to an overuse of lipid lowering medications and an enormous expense of m-LDL-cholesterol assay.

Keywords: *Low density lipoprotein cholesterol, LDL*

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Low density lipoprotein (LDL) is a lipoprotein consisting of cholesterol (40%-50%), phospholipids (20%-25%) and triglyceride (5%-15%). Elevation of blood LDL-cholesterol is recognized as one of the major risk factors for atherosclerosis and ischemic heart disease and a lowering of blood LDL-cholesterol could diminish the risk of ischemic heart disease[1-3]. The third report of the national cholesterol education program (NCEP III) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (adult treatment panel III) classifies blood LDL-cholesterol levels as normal (blood LDL-cholesterol < 100 mg/dl), nearly-normal (blood LDL-cholesterol 100-129 mg/dl), nearly-high (blood LDL-cholesterol 130-159 mg/dl), high (blood LDL-cholesterol 160-189 mg/dl) and very high (blood LDL-cholesterol >190 mg/dl)[4]. Management of individuals with elevated blood LDL-cholesterol includes diet control, exercise, and drugs. It is suggested that 1) individuals with ≤ 1 cardiovascular risk factor who have a chance of developing ischemic heart disease of less than 10% within 10 years should receive treatment if their blood LDL-cholesterol is ≥ 190 mg/dl 2) individuals with ≥ 2 cardiovascular risk factor who have a chance of developing ischemic heart disease of less than 10% within 10 years should receive treatment if their blood LDL-cholesterol is ≥ 160 mg/dl 3) people with ≥ 2 cardiovascular risk factors who have a chance of developing ischemic heart disease of 10% to 20% within 10 years, or patients with diabetes mellitus or ischemic heart disease who have a chance of developing ischemic heart disease of more than 20% within 10 years should receive treatment if their blood LDL-cholesterol is ≥ 130 mg/dl and they should have behavior modification if their blood LDL-cholesterol is ≥ 100 mg./dl. The aforementioned blood LDL-cholesterol thresholds are based on LDL-cholesterol calculated from total cholesterol, triglyceride and high density lipoprotein (HDL) cholesterol using Friedewald's formula[5]. Calculated LDL-cholesterol (c-LDL) is equivalent to total cholesterol – HDL-cholesterol – triglyceride/5. A direct measurement for blood LDL-cholesterol (m-LDL) has been available over the past decade and this assay has become popular. The cost of an m-LDL-cholesterol assay in Siriraj Hospital is 150 baht, whereas c-LDL-cholesterol is provided without any additional cost if total cholesterol, triglyceride and HDL-cholesterol are ordered.

The objectives of the study were to determine the pattern of utilization of m-LDL-cholesterol and to determine cut-off thresholds of m-LDL-cholesterol that predict c-LDL-cholesterol cut-off levels for initiating appropriate management as recommended in NCEP III.

Material and Method

The test results of total cholesterol, triglyceride, HDL-cholesterol and m-LDL-cholesterol from the same individuals aged ≥ 18 years during January to December 2004 were retrieved from the database of the Department of Clinical Pathology, Faculty of Medicine Siriraj Hospital. Calculated LDL-cholesterol was computed using Freidewald formula. There were two data sets. The first data set was the m-LDL-cholesterol cut-off level derivation data set. It was the test results of 784 individuals randomly selected from those who had the tests during January to June 2004. The medical records of these individuals were analyzed for demographics, cardiovascular risk factors and managements they received. The second data set was the m-LDL-cholesterol cut-off level validation data set. It was the test results of 800 individuals randomly selected from those who had the tests during July to December 2004. The data were analyzed by descriptive statistics and inferential statistics where appropriate. The correlation between c-LDL-cholesterol and m-LDL-cholesterol levels was determined by Pearson's Product Moment Correlation Coefficient. The formula for transforming m-LDL-cholesterol level to c-LDL-cholesterol level was generated from linear regression analysis. A p-value ≤ 0.05 was considered statistically significant.

Results

1. Analyses of the test results of the m-LDL-cholesterol cut-off level derivation data set (784 individuals) revealed the following:

Twenty individuals (2.6%) had blood triglyceride > 400 mg/dl hence c-LDL-cholesterol could not be computed.

Seven hundred and sixty four individuals with blood triglyceride < 400 mg/dl had demographics and clinical features as shown in Table 1. 63.4% of them were females. A mean age was 59.4 years, mean body weight was 61.5 Kg, mean height was 159.4 cm, and mean body mass index (BMI) was 24.75 Kg/m^2 22.3% of them had ischemic heart diseases, 1.6% had ≤ 1 cardiovascular risk factor, 23.6% had ≥ 2 cardiovascular risk factors; and the status of cardiovascular risk factors was not available in 52.6%.

The lipid profiles of 764 individuals with blood triglyceride < 400 mg./dl. are shown in Table 2. The m-LDL-cholesterol levels were higher than c-LDL-cholesterol levels.

Table 1. Demographics and cardiovascular risk factors of 764 individuals who had blood triglyceride < 400 mg/dl

Characteristic	
Females	484 (63.4%)
Mean age (SD)	59.4 yr (13.07 yr)
Median age (Range)	60.3 yr (18-89 yr)
Mean body weight (SD)	59.4 Kg (13.07 Kg)
Median body weight (Range)	60.0 Kg (33-102 Kg)
Mean height (SD)	159.4 cm (8.09 cm)
Median height (Range)	158.0 cm (140-181 cm)
Mean BMI (SD)	24.75 Kg/m^2 (3.94 Kg/m^2)
Median BMI (Range)	24.51 Kg/m^2 (17.19-37.25 Kg/m^2)
Cardiovascular Risk Factors Ischemic Heart Disease	170 (22.3%)
≥ 2 factors	180 (23.6%)
0-1 factor	12 (1.6%)
not available	402 (52.6%)

Table 2. Lipid profiles of 764 individuals who had blood triglyceride < 400 mg/dl

	Range	Mean (SD)	Median
Cholesterol (mg/dl)	72-383	204.6 (46.77)	201.0
HDL-cholesterol (mg/dl)	9-122	53.2 (16.51)	51.6
Triglyceride (mg/dl)	18-398	131.9 (67.79)	115.0
m-LDL-cholesterol (mg/dl)	33-295	145.6 (44.98)	142.0
c-LDL-cholesterol (mg/dl)	9-267	124.9 (41.08)	122.3

The distribution of the difference between m-LDL-cholesterol and c-LDL-cholesterol levels from 764 individuals with blood triglyceride < 400 mg/dl is shown in Table 3. 91% of them had a difference ≤ 25%.

The correlation between c-LDL-cholesterol levels and m-LDL-cholesterol levels is shown in Fig. 1. The correlation was statistically significant ($p < 0.001$) and the magnitude of the correlation was very high.

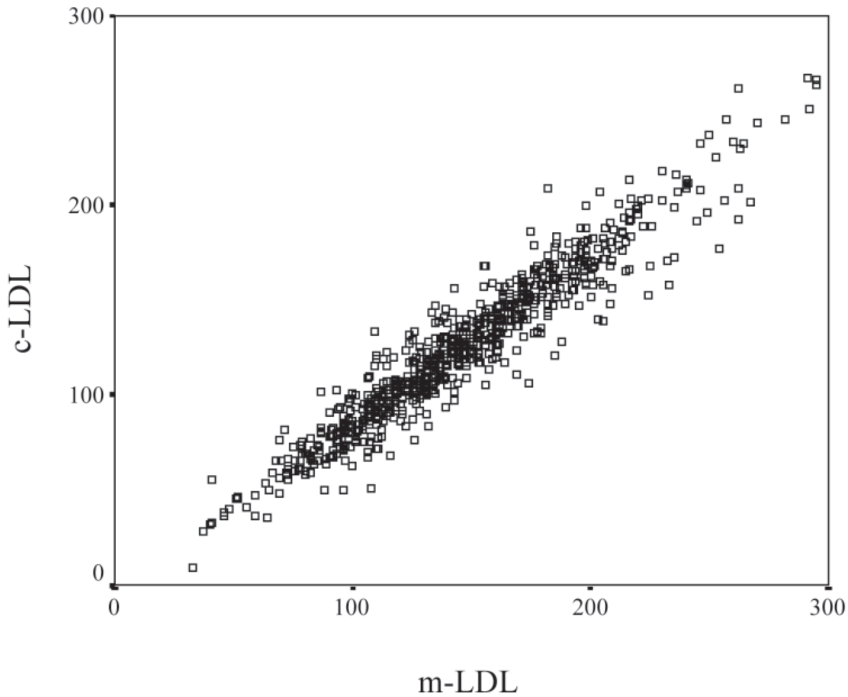
The predictive levels of m-LDL-cholesterol to determine c-LDL-cholesterol levels of < 100, ≥ 100, ≥ 130, ≥ 160 and ≥ 190 mg/dl were < 87, > 143, > 188, > 233 and > 254 mg/dl respectively (Table 4).

2. Analyses of the test results of the m-LDL-cholesterol cut-off level validation data set (800 individuals) revealed the following:

The individuals with blood triglyceride < 400 mg/dl had a mean age of 57.9 years and 61.8% of them were females. There was no statistically significant difference in demographics between the individuals in

Table 3. The distribution of the differences between m-LDL-cholesterol levels and c-LDL-cholesterol levels from 764 individuals with blood triglyceride < 400 mg/dl

Difference between c-LDL- cholesterol and m-LDL- cholesterol	N (%)
± 5%	53 (6.9)
± 10%	139 (18.2)
± 15%	221 (28.9)
± 20%	183 (24.0)
± 25%	98 (12.8)
± 30%	36 (12.8)
± 35%	21 (2.7)
± 40%	7 (0.9)
± 45%	3 (0.4)
± 50%	1 (0.1)
± 55%	1 (0.1)
± 60%	1 (0.1)



Pearson Correlation Coefficient (r) = 0.956, $p < 0.001$

Fig. 1 The correlation between c-LDL-cholesterol levels and m-LDL-cholesterol levels from 764 individuals with blood triglyceride < 400 mg/dl

Table 4. The predictive values of m-LDL-cholesterol level to determine c-LDL-cholesterol level

m-LDL-cholesterol (mg/dl)	c-LDL-cholesterol (mg/dl)
<87	<100
>143	≥100
>188	≥130
>233	≥160
>254	≥190

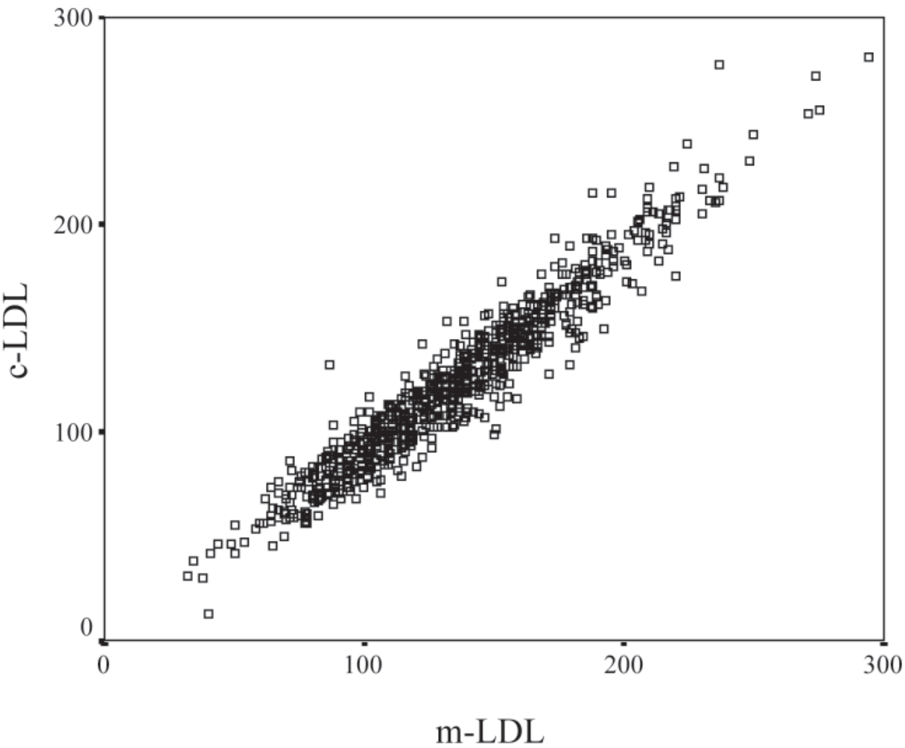
the m-LDL-cholesterol cut-off value derivation data set and the m-LDL-cholesterol cut-off value validation data set.

The lipid profiles of 800 individuals with blood triglyceride < 400 mg/dl are shown in Table 5. The m-LDL-cholesterol values were higher than c-LDL cholesterol values similar to those observed in 764 individuals in the m-LDL-cholesterol cut-off value derivation data set.

The correlation between c-LDL-cholesterol and m-LDL-cholesterol levels is shown in Fig. 2. The correlation was statistically significant ($p < 0.001$) and the magnitude of the correlation was very high.

Table 5. Lipid profiles of 800 individuals who had blood triglyceride < 400 mg/dl

	Range	Mean (SD)	Median
Cholesterol (mg/dl)	45-366	201.8 (45.78)	200
HDL-cholesterol (mg/dl)	6-116	51.5 (14.31)	50
Triglyceride (mg/dl)	32-398	131.8 (66.68)	117
m-LDL-cholesterol (mg/dl)	32-294	134.9 (40.66)	133
c-LDL-cholesterol (mg/dl)	13-281	124 (40.21)	120



Pearson Correlation Coefficient (r) = 0.963, p < 0.001

Fig. 2 The correlation between c-LDL-cholesterol levels and m-LDL-cholesterol levels from 800 individuals with blood triglyceride < 400 mg/dl

An application of m-LDL-cholesterol cut-off values derived from the m-LDL-cholesterol cut-off value derivation data set to the m-LDL-cholesterol cut-off value validation data set showed that m-LDL-cholesterol < 87, > 143, > 188, > 233 and > 254 mg/dl had accuracy in predicting c-LDL-cholesterol < 100, ≥ 100, ≥ 130, ≥ 160 and ≥ 190 mg/dl of 100%, 99.7%, 100%, 100% and 100% respectively.

3. The nomogram to be used for transforming m-LDL-cholesterol level to c-LDL-cholesterol level was made from the test results of 1,564 individuals who had blood triglyceride < 400 mg/dl and is shown in Fig. 3.

4. A formula for transforming m-LDL-cholesterol level to c-LDL-cholesterol level was generated from the test results of 1,564 individuals who had blood triglyceride < 400 mg./dl. using a linear regression analysis. The c-LDL-cholesterol was approximately 0.89 x m-LDL-cholesterol.

5. Analyses of a sample of individuals whose baseline m-LDL-cholesterol levels were available and who had received lipid lowering drugs based on m-LDL-cholesterol levels revealed the following observations:

Out of 28 individuals with baseline m-LDL-cholesterol level > 100 mg/dl, 27 had c-LDL-cholesterol level ≥ 100 mg/dl. Hence the treatment was inappropriately given in 1/28 (3.6%) of cases.

Out of 26 individuals with baseline m-LDL-cholesterol level > 130 mg/dl, 25 had c-LDL-cholesterol level ≥ 130 mg/dl. Hence the treatment was inappropriately given in 1/26 (3.8%) of cases.

Out of 20 individuals with baseline m-LDL-cholesterol level > 160 mg/dl, 16 had c-LDL-cholesterol level ≥ 160 mg/dl. Hence the treatment was inappropriately given in 4/20 (20%) of cases.

Out of seven individuals with baseline m-LDL-cholesterol level >190 mg./dl, four had c-LDL-cholesterol level ≥ 190 mg/dl. Hence the treatment was inappropriately given in 3/7 (42.9%) of cases.

Discussion

Our study confirmed the findings from other reports that c-LDL-cholesterol levels are strongly

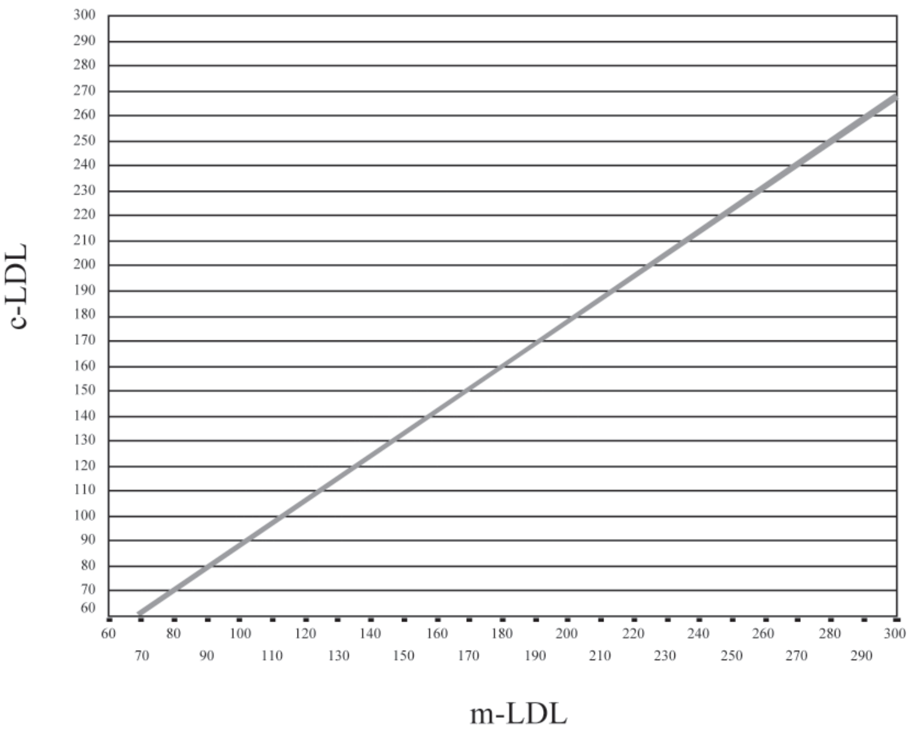


Fig. 3 Nomogram for transforming m-LDL-cholesterol level to c-LDL-cholesterol level

correlated with m-LDL-cholesterol levels[6-9]. However, the correlation between c-LDL-cholesterol levels and m-LDL-cholesterol levels is not perfect. As a result, the values of m-LDL-cholesterol levels are not exactly the same as c-LDL-cholesterol levels and m-LDL-cholesterol levels are usually higher than c-LDL-cholesterol levels. The LDL-cholesterol cut-off values for initiating appropriate management recommended in NCEPIII are based on c-LDL-cholesterol levels. Therefore, m-LDL-cholesterol levels could not replace c-LDL-cholesterol levels if one wants to use the LDL-cholesterol cut-off values recommended in NCEPIII as a guide for management of patients with dyslipidemia. Our study demonstrated that 3.6% to 42.9% of the patients with an elevated LDL-cholesterol level received unnecessary lipid-lowering agents if the LDL-cholesterol cut-off values recommended in NCEIII were used for m-LDL-cholesterol levels. The m-LDL-cholesterol cut-off values of < 87, > 143, > 188, > 233 and > 254 mg/dl were found to be accurate to predict the c-LDL-cholesterol levels of < 100, ≥ 100, ≥ 130, ≥ 160 and ≥ 190 mg/dl respectively. Moreover, we observed that only 2.6% of the individuals who received lipid profile testing had blood triglyceride > 400 mg/dl and c-LDL-cholesterol could not be computed. Hence the m-LDL-cholesterol assay is needed for this group and the cut-off thresholds for initiating lipid-lowering agents should be > 143, > 188, > 233 and > 254 mg/dl instead of < 100, ≥ 100, ≥ 130, ≥ 160 and ≥ 190 mg/dl respectively. Until more solid evidence on the clinical benefit to patients receiving management according to the cut-off values of m-LDL-cholesterol is available, the cut-off values of c-LDL-cholesterol should not be applied to m-LDL-cholesterol test results to guide the treatment on patients. If the m-LDL-cholesterol assay becomes necessary such as in those with blood triglyceride > 400 mg/dl, the cut-off values of > 143, > 188, > 233 and > 254 mg/dl should be considered or the m-LDL-cholesterol level should be transformed to c-LDL-cholesterol level using the nomogram in figure 3 or the m-LDL-cholesterol level should be transformed to the c-LDL-cholesterol level using the formula of c-LDL-cholesterol ~ 0.89 x m-LDL-cholesterol prior to initiating appropriate management. The aforementioned nomogram or formula for transforming m-LDL-cholesterol level to c-LDL-cholesterol level is also useful for health care providers who use m-LDL-cholesterol for monitoring the response to treatment, since the cost of a m-LDL-cholesterol assay (150 baht) is less than the cost of a combination of total cholesterol, HDL-cholesterol and triglyceride (170 baht). In conclusion, m-LDL-cholesterol assay has a very limited use in managing individuals with suspected or known dyslipidemia. The use of m-LDL-cholesterol level as a guide for the management of abnormal LDL-cholesterol conditions leads to an overuse of lipid lowering medications and an enormous expense in m-LDL-cholesterol assay costs.

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การใช้การตรวจ low density lipoprotein cholesterol ที่ได้จากการคำนวณและ low density lipoprotein cholesterol ที่ได้จากการวัดโดยตรงในโรงพยาบาลศิริราช

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คณะผู้วิจัยได้ศึกษาการใช้การตรวจ low density lipoprotein (c-LDL) cholesterol ที่ได้จากการคำนวณและ low density lipoprotein (m-LDL) cholesterol ที่ได้จากการวัดโดยตรง ในโรงพยาบาลศิริราชโดยนำผลการตรวจระดับของ total cholesterol, triglyceride, high density lipoprotein (HDL) cholesterol และ m-LDL-cholesterol จากคนเดียวกันที่อายุ 18 ปีหรือมากกว่าและได้รับการตรวจระดับไขมันในเลือดที่ภาควิชาพยาธิวิทยาคลินิกระหว่างเดือนมกราคมถึงธันวาคม พ.ศ. 2547 ส่วนหนึ่งมาคำนวณค่า c-LDL-cholesterol ด้วยสูตรของ Friedewald แล้วนำผลดังกล่าวมาวิเคราะห์ความสัมพันธ์กับระดับ m-LDL-cholesterol ข้อมูลที่นำมาศึกษามี 2 ชุด ได้แก่ ข้อมูลชุดแรกที่นำมาวิเคราะห์หาเกณฑ์ของค่า m-LDL-cholesterol (derivation data set) จำนวน 784 คนและข้อมูลชุดที่สองที่นำมาทดสอบความแม่นยำของเกณฑ์ของค่า m-LDL-cholesterol ที่ได้จากข้อมูลชุดแรก (validation data set) จำนวน 800 คน พบว่า 1) ผู้มารับการตรวจร้อยละ 2.6 มีค่า triglyceride มากกว่า 400 มก./ดล. ซึ่งไม่สามารถคำนวณค่า c-LDL-cholesterol ได้ 2) ค่า c-LDL-cholesterol และ m-LDL-cholesterol ของข้อมูลทั้ง 2 ชุดมีความสัมพันธ์กันอย่างมีนัยสำคัญทางสถิติ ($p < 0.001$) และความสัมพันธ์มีขนาดมากกว่า 0.95, 3) ระดับของ m-LDL-cholesterol มักสูงกว่า c-LDL cholesterol 4) ค่า m-LDL-cholesterol cut-off < 87, > 143, > 188, > 233 and > 254 มก./ดล. จะสัมพันธ์กับค่า c-LDL-cholesterol < 100, ≥ 100, ≥ 130, ≥ 160 และ ≥ 190 มก./ดล. ตามลำดับ 5) เมื่อนำเกณฑ์ดังกล่าวจากข้อมูลชุดแรกไปประยุกต์ใช้กับข้อมูลชุดที่สองพบว่าค่า m-LDL-cholesterol < 87, > 143, > 188, > 233 and > 254 มก./ดล. มีความแม่นยำในการทำนายค่า c-LDL-cholesterol < 100, ≥ 100, ≥ 130, ≥ 160 และ ≥ 190 มก./ดล. ร้อยละ 100, 99.7, 100, 100 และ 100 ตามลำดับ 6) เมื่อวิเคราะห์ผู้ป่วยที่มีค่า m-LDL-cholesterol ก่อนการรักษาและได้รับการรักษาด้วยยาลดไขมันในเลือดโดยอาศัยระดับของ m-LDL-cholesterol เป็นแนวทางในการรักษาพบว่าผู้ป่วยร้อยละ 3.6 ถึง 42.9 ได้รับยาลดไขมันโดยไม่จำเป็น 7) ได้สร้าง nomogram สำหรับแปลงค่า m-LDL-cholesterol ให้เป็น c-LDL-cholesterol และสูตรการแปลง m-LDL-cholesterol ให้เป็น c-LDL-cholesterol โดย c-LDL-cholesterol จะมีค่า 0.89 x m-LDL-cholesterol ผลการศึกษานี้แสดงว่า m-LDL-cholesterol มีที่ใช้น้อยมาก การใช้การตรวจ m-LDL-cholesterol โดยอาศัยเกณฑ์ระดับ c-LDL-cholesterol เป็นแนวทางในการรักษาผู้ป่วยทำให้ผู้ป่วยส่วนหนึ่งได้รับยาลดไขมันในเลือดโดยไม่จำเป็นและยังสิ้นเปลืองค่าใช้จ่ายในการตรวจ m-LDL-cholesterol ด้วย