NIS REPORT SYNOPSIS

Cholesterol Goal Attainment rate and its associated factors among dyslipidemic Patients on lipid-lowering drug therapy in Korea (CRESCENDO study)

Study Site(s)

There were 4,970 patients at 44 centres in Korea.

Publications

None at the time of writing this report.

Study dates

First Subject In: 17August 2011

Last Subject Last Visit: 9 December 2011

Medicinal products and concomitant medication

Not applicable (non-interventional treatment)

Objectives

1) To investigate the percentage of reaching a target LDL-C value based on the NCEP-ATP III Guideline in Korean dyslipidemic patients taking lipid lowering agents.
2) To identify factors related to the percentage of reaching a target LDL-C value in Korean dyslipidemic patients on lipid lowering therapy, and to observe the percentage of reaching a target LDL-C value by patient population classified by CHD risk factors and medical history (including coronary artery disease, diabetes mellitus, stroke, and hypertension).

Study design

This was a multi-centre, cross-sectional, non-interventional study to investigate the percentage of reaching a target LDL-C value based on the NCEP-ATP III Guideline in Korean dyslipidemic patients taking lipid lowering agents and to identify the associated factors. During visit to physician, demographic data including physical examination, history (disease and medication) and vital signs were collected. Lipid profiles such as total cholesterol, triglyceride, HDL-C and LDL-C and results of

other haematological tests including fasting glucose, HbA1c and hsCRP were analysed at laboratory. Cardiovascular risk factors were also collected.

Target subject population

Patients had a diagnosis of hyperlipidemia or dyslipidemia.

Study variable(s)

Primary outcome variable:

- Serum lipid profiles (total cholesterol, triglyceride, LDL-C, and HDL-C)

Secondary outcome variables:

- The number of cardiovascular risk factors.
- Demographic factors: age, sex, smoking, and family history of cardiovascular diseases.
- Results of other hematological tests: fasting glucose, HbA1c, and hsCRP.
- Body measurements: height, weight, and waist circumference.
- Past and present medical history: cardiovascular diseases, diabetes mellitus, stroke (hemorrhagic or ischemic; in case of ischemic, followed TOAST criteria), and hypertension.
- Records of current and past medications.

Statistical methods

Descriptive statistical analysis was performed based on mean, standard deviation, median, minimum and maximum values. The category data were described based on the percentage and number of patients in each category. Overall, the percentage and number of patients who reached a target LDL-C value were determined based on patient history and CHD risk factors. Relationship between the achievement of a target LDL-C and other factors were evaluated by univariate analysis, and appropriate statistical analysis was performed. Although this was the descriptive study without specific hypothesis, exploratory analysis was performed for other analytical evaluations. All statistical analysis was performed by using SAS

Subject population

A total of 4,970 patients were enrolled for participating in this study. Among them, 4,067 patients were evaluated.

The patient demographics are summarized below in Table S1. The baseline characteristics of patients indicated that the mean age ± SD was 62.0 ± 10.9, and 43.1% of the evaluable subjects were non-

smokers where as 15.6% of ex-smokers and 11.6% of current smokers. 5.2% of the evaluable subjects had history of cardiovascular diseases where as 46.7% did not (Table S1).

Table S1. Patient Demographics

Item	Category		All Subjects*	Evaluable Subjects
Age (years)		N	4945	4067
		Mean[SD]	61.9[10.9]	62.0[10.9]
Sex		N	4945	4067
	Male	n(%)	2642(53.4)	2197(54.0)
	Female	n(%)	2303(46.6)	1870(46.0)
Smoking		N	4945	4067
	Non-smoker	n(%)	2140(43.3)	1754(43.1)
	Ex-smoker	n(%)	707(14.3)	634(15.6)
	Current smoker	n(%)	555(11.2)	473(11.6)
	Unknown	n(%)	1543(31.2)	1206(29.7)
Family history of cardiovascular disease		N	4945	4067
	Yes	n(%)	240(4.9)	213(5.2)
	No	n(%)	2300(46.5)	1898(46.7)
	Unknown	n(%)	2405(48.6)	1956(48.1)

Summary of results

The percentage of reaching a target LDL-C value was 69.9% (2,841/4,067 subjects), with no difference by age. Based on the results of NCEP-ATP III LDL-C goals in different risk categories and the percentage of reaching a target LDL-C value, the percentages of reaching target LDL-C values based on the modified NCEP-ATP III classification were presented in evaluable subjects. 69.9% (2841/4067 subjects) of the entire evaluable subjects reached the target LDL-C values, and the most dominant categories of reaching the values were moderate risk and low risk in 93.6% (393/420 subjects) and 93.4% (677/725 subjects), respectively, followed by moderate high risk, high risk, and very high risk in 85.7% (221/258 subjects), 74.7% (1125/1506 subjects), and 36.7% (425/1158 subjects), respectively (Table S2).

Table S2. Percentages of Reaching Target LDL-C Value Based on Modified NCEP-ATP III Classification (Evaluable Subjects)

	Target LDL-C	N=4067	n(%)	95% CI
Very high risk	< 70 mg/dL	1158	425(36.7)	33.9, 39.5

Table S2. Percentages of Reaching Target LDL-C Value Based on Modified NCEP-ATP III Classification (Evaluable Subjects)

High risk	< 100 mg/dL	1506	1125(74.7)	72.5, 76.9
Moderate high risk	< 130 mg/dL	258	221(85.7)	81.2, 90.1
Moderate risk	< 130 mg/dL	420	393(93.6)	91.1, 96.0
Low risk	< 160 mg/dL	725	677(93.4)	91.5, 95.3
Overall		4067	2841(69.9)	68.4, 71.3

Factors associated with the percentage of reaching a target LDL-C value were also defined as the secondary objectives of this study. Based on univariate analysis, it was revealed statistically significant with the factors including smoking, family history, coronary artery disease, diabetes, stroke, age, total cholesterol, HDL cholesterol, triglyceride, fasting glucose and hsCRP. However, factors such as sex, hypertension, peripheral artery disease, waist circumference, BMI, blood pressure, and HbA1c did not show statistically significant difference between the success and failure of reaching LDL-C goal.

For safety, adverse events were not collected specifically for this study because of the way it was designed as a non-interventional study without the study medication as per protocol. However, serious adverse events related to the study procedure had to be collected, and the causal relationship was assessed based the protocol.