



STUDY REPORT SYNOPSIS

Finished product: not applicable

Active ingredient: not applicable

Study No. NIS-CRS-DUM-2010/1

An epidemiological study aimed to record standard daily practice in managing patients with hypercholesterolemia

Developmental phase: IV (non-interventional study)

Study completion date: 06 Oct 2011

Date of Report: 25 July 2012

OBJECTIVES:

- (a) Primary objective To evaluate proportion of patients on lipid-lowering pharmacological treatment reaching the LDL-C goals according to the NCEP ATP III / updated 2004 NCEP ATP III guidelines
- (b) Main secondary objectives:
 - To determine the proportion of patients on lipid-lowering pharmacological treatment reaching the non HDL-C goals according to the NCEP ATP III / updated 2004 NCEP ATP III guidelines;
 - To explore physicians' standard practice in managing patients with hypercholesterolemia (by using physicians' questionnaire);
 - To collect local epidemiological data on patients with hypercholesterolemia (Demographic Data; Hypercholesterolemia management data: treatment, treatment changes)

METHODS:

Patients had three study related-visits: visit 1 (baseline), visit 2 (6 weeks \pm 2 weeks after visit 1) and visit 3 (12 weeks \pm 2 weeks after visit 1). At each visit the following tools were used: recording of data in CRF (by investigator) and recording of data in form of investigator questionnaire only at visit 1.

RESULTS:

Primary objective

Overall, 189 (60.2%) out of 314 patients with available LDL-C data reached the LDL-C goals according to the NCEP ATP III / updated 2004 NCEP ATP III guidelines.

Among patients without coronary disease (128), 106 (82, 8%) reached target LDL-c (3,4 mmol/l). In the group of patients with coronary disease (118) , 68 (57.6%) reached target LDL-c 2.6 mmol/l.

Main secondary objectives:

- Out of 301 patients with available HDL-C data, 140 (46.5%) reached non HDL-C goals according to the NCEP ATP III / updated 2004 NCEP ATP III guidelines.
- Physicians' standard practice

In this non interventional study 40 doctors/investigators were included, 30 of them completed the investigator's questionnaire at visit 1. Among investigators, two-thirds were female doctors, and 82% of doctors were cardiologist.

Investigators have responded more strongly to the achievement of individual target values using laboratory values of total cholesterol (80%) and LDL-cholesterol (90%) than HDL-cholesterol (56.7%) and triglycerides (46.7%). All investigators (97%), except one, used some recommendations / guidelines in order to establish individual cholesterol level based-treatment goals.

9 (31%) of them use NCEP ATP III guidelines (FRAMINGHAM), 15 (51.7%) of them use Joint European guidelines (SCORE), and 4 (13.8%) of them use national guidelines).

30% (9) strongly agreed that they are not being able to efficiently treat patients with cardiovascular disease. 46, 7% of doctors (14) state that a sufficient number of patients achieve target levels of cholesterol. 37.9%(11) of doctors in general do not agree with the fact that guidelines advise low doses of lipid lowering drugs for all patients, and then titrate the dose for all patients and 62.1% of doctors (18) in general do not agree with the fact that guidelines advise lifestyle changes as first-line therapy for all patients

39.3% (11) of doctors feel that compliance reduces if lipid lowering drugs take longer times to show its effect. 46.7% (14) of doctors feel limited when using the less efficient lipid lowering drug in the first phase of treatment". 36.7% of doctors (11 investigators) state "Patients' concern that their medical condition is more difficult if the dose of lipid lowering drug has to be increased ". 50% of doctors (15 investigators) state "Patients' concern that their medical condition is more difficult if we frequently change lipid lowering drug".

Investigators schedule a control visit after 3 months upon achieving targeted cholesterol levels; 80% of patients come to that control visit.

- The study was conducted in 14 centres with the participation of 40 cardiologists. They included a total of 330 patients in the study. The average age of patients included in the study was 58 years. 168 patients (51.2%) had coronary disease in personal history of illness, 52 patients (15.9%) had peripheral vascular disease, 33 patients (10.1%) had cerebrovascular disease, and 69 patients (21%) had diabetes.
- Hypercholesterolemia management data: treatment, treatment changes

Of the total number of patients enrolled in this study, 181 patients (62%) were less than one year on statin therapy. 83 patients (28.4%) were on this therapy between one and five years, and only 28 patients were more than five years on statin therapy.

There is a reduction in total cholesterol by 28%, LDL-cholesterol by 38% and that there is an increase in HDL-cholesterol by 7.69%.

Mean total cholesterol values were highly statistically significantly lower in the second and third visits than in the first visit. ($p < 0.001$)

Mean LDL-cholesterol were highly statistically significantly lower in the second and third visits than in the first ($p < 0.001$)

Mean HDL-cholesterol were highly statistically significantly higher in the third visits than in the first. ($p < 0.001$)

Mean triglyceride values were highly statistically significantly lower in the second and third visits than in the first. ($Z = 12.121, p < 0.000$).