

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A

ACTIVE INGREDIENT: N/A

Study No: NIS-CKR-DUM-2009/1

Investigation into LDL-C goal achievement rate in Korean Diabetic patients according to updated ADA RecommendaTion (DART study)

Developmental phase: Marketed

Study Completion Date: 2009-12-03

Date of Report: 2009-10-23

OBJECTIVES:

Primary objectives

To investigate LDL-C goal achievement rate according to ADA recommendation

Secondary objectives

To investigate reduction of 10-year risk for CHD by using UKPDS risk engine

To investigate lipid profile changes before/after statin treatment

METHODS:

Design

The present study was a multi-centre survey of subjects who had been diagnosed for diabetes and dyslipidaemia in tertiary-care hospitals in Korea. This study was conducted retrospectively. Investigators engaged in this study screened their outpatients with their medical chart. After screening appropriate subjects in the past 6 months according to inclusion criteria, investigators filled the patient record form based on medical chart. Investigators completed a patient record form with subjects' demographic characteristics, diabetes duration, lab profile, current medication for diabetes & dyslipidaemia, atherosclerosis diagnosis history and concomitant medication.

All subjects were divided two groups according to LDL-C goal

- Goal for diabetic patient without major risk factor: 100mg/dl
- Goal for diabetic patient with major risk factor: <70mg/dl

Inclusion criteria

For inclusion in this study, subject should fulfil all of the following criteria.

1. Subjects of either gender / aged over 18 years
2. Subjects who are taking lipid-lowering medication after diagnosed as dyslipidaemia
3. Subjects who have at least made 1 visit to the outpatient clinic within previous 6 months

4. Subjects who have records of both LDL-C and HDL-C before & after statin treatment (at least four weeks after statin taking)

Exclusion criteria

1. Involvement in the planning and conduct of the study (applies to both AstraZeneca staff or staff at the study site).
2. Previous enrolment or randomisation of treatment in the present study.
3. Participation in a clinical trial during the last 90 days.
4. Subjects who are unwilling or unable to provide their examination and lab result of medical chart.

Result variables

- **Primary variables:** LDL-C goal achievement rate according to ADA recommendation
- **Secondary variables:** 10-year risk for CHD by using UKPDS risk engine, lipid profile changes before/after statin treatment

Statistical Analysis

Firstly, we divided subjects into two groups. One was LDL-C goal <100mg/dl, another is LDL-C goal <70mg/dl. Then we compared goal achievement rate regarding two groups. Secondly, in each group, we calculated 10 year CHD risk reduction rate by using UKPDS risk engine and compared two groups with an anticipation of positive result from goal-achieved groups. All patients were categorized according their risk score, and the frequency and 95% confidence interval were described by the groups mentioned above, respectively.

The design of this study had no predefined hypothesis. We summarized the data using descriptive statistics and analysis the data with exploratory method about any doubtful factors for primary objective. For comparing among (LDL-C goal <100mg/dl and goal < 70 mg/ dl) groups, we used 5% significance level. And we made tables and figures for descriptive analysis such as demographic characteristics, diabetes duration, CHD diagnosis history, lab profile etc.

RESULTS:

Of a total of 2547 patients enrolled from 53 centers, 2249 were included in the analysis set. 298 patients were excluded from the analysis set on the ground of the age less than 18 years and having no data for the confirmation of the LDL-C goal achievement according to ADA recommendation.

There were more (52.3%) men than women (47.7%), the mean age was 58 years.

Patients whose LDL goal achievement according to ADA recommendation at the highest risk were 1935 and the patients at the high risk with LDL goal achievement less than 100mg/dl were 314.

The predicted prevalence of cardiovascular disease according to the UKPDS risk engine was 21.6% and Framingham 10-year risk was 6.5%.

The life style modification and HMG-CoA reductase inhibitors had the biggest impact in the low LDL and high HDL among the treatment history for dyslipidaemia.