

NIS REPORT SYNOPSIS

Dyslipidemia Management in Chinese Post Stroke Patients

Sponsor:	AstraZeneca Investment (China) Co., Ltd.
Study Date:	July, 2013 to November, 2014
Study Objective:	To observe LDL-C level of Chinese post-stroke patients within 6-12 months from attack and control rate of LDL-C
Study Method:	Non-interventional, multi-centre, cross-sectional, observational study
Subject Number:	3400 subjects planned, actually 4117 subjects recruited
Inclusion /Exclusion Criteria:	<p>The subject population that was observed in the NIS fulfilled all of the following criteria:</p> <ol style="list-style-type: none">1. Male or female with age \geq 18 years2. Post ischemic stroke patients within 6-12 months from attack3. Written informed consent was provided to participant in the study <p>The prescription of the medicinal product clearly separated from the decision to include the subject in the NIS or not.</p> <p>Any of the following was regarded as a criterion for exclusion from the study:</p> <ol style="list-style-type: none">1. Significant medical or psychological condition that made patients could not finish the questionnaire independently or with the aids of his/her legal representatives2. The patient was in another clinical study3. Previous enrolment in the present study
Evaluation Criteria:	<p>Primary variable: LDL-C</p> <p>Secondary variables: HDL-C, Total Cholesterol, Triglyceride, Blood Pressure, HbA1c (if available)</p>

Statistical Methods:	Continuous variables were described as mean \pm SD; categorical variables were described as percentages. The percentage of LDL-C treatment goal achievement in China post-stroke patients was presented using descriptive statistics. No treatment comparisons were performed. The associations between control situation of LDL-C, blood pressure or glucose and patients characteristics were explored by logistic regression model. Descriptive statistics were used for other secondary variables. All statistical tests were two-sided, and p value of ≤ 0.05 was considered statistically significant.
TARGET PATIENT POPULATION, STUDY DISEASE AND SAMPLE SIZE	This was an observational study, aiming to investigate current LDL-C level in China post stroke patients within 6-12 months from attack and assess the control situation of LDL-C in this population. A sample size of 3400 would be sufficient to detect control rate of LDL-C with a precision at 0.015 when the rate was around 28.5%. The study was planned to recruit approximately 3400 eligible subjects from 50 hospitals in China. Actually, 4117 (Age ≥ 18 years old) post stroke patients with 6-12 months from attack were recruited from 56 sites in this study.
CRITERIA FOR EVALUATION (MAIN VARIABLES)	<p>Primary Variable</p> <ul style="list-style-type: none"> • LDL-C <p>Secondary Variables</p> <ul style="list-style-type: none"> • HDL-C • Total Cholesterol • Triglyceride • Blood Pressure • HbA1c (if available)
Result	<p>-Primary Variable:</p> <p>In FAS population, the analyses of LDL-C, blood pressure and HbA1c control rate indicated that 1082 patients reached LDL-C less than 1.8 mmol/L, and the control rate was 27.35% with 95% CI (25.97%, 28.77%); 2442 patients reached blood pressure less than 140/90 mmHg, and the control rate was 61.74% with 95% CI (60.21%, 63.26%). Of 965 patients who had HbA1C test results, 624 patients reached HbA1c less than 6.5%, and the control rate was 64.66% with 95% CI (61.55%, 67.68%).</p> <p>-Secondary Objectives:</p> <p>The number of patients who reached target blood pressure was 2442; the control rate was 61.74%, with 95% CI (60.21%, 63.26%). The subgroup analysis of control rate showed that lipid modifying medications compliance, age (categorical variable), smoking status, physical activity, history of carotid</p>

	<p>artery stenosis, and hypertension had statistically significant effects on the control rate of blood pressure, ($p < 0.05$). The control rate of the patients who had carotid artery stenosis was lower than those without carotid artery stenosis. The rates were 54.29% and 63.87% respectively, the OR was 0.672, with 95% CI (0.578, 0.781).</p>
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