

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No applicable

ACTIVE INGREDIENT: No applicable

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| Study No: NIS-CFR-DUM-2007/9 |
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| Prysmo : Implementation time of a lipid lowering therapy in patients with dyslipidemia in general practice. |
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Developmental phase: No applicable

Study Completion Date: LSLV = 15 January 2009

Date of Report: 14 December 2009

OBJECTIVES:

The objective of the PRYSME survey was to describe the time to initiation of cholesterol-lowering drug therapy in the management of dyslipidaemic patients, according to the cardiovascular risk level.

METHODS and RESULTS:

A total of 3,624 patients were included in this survey by 1,226 active physicians. Data for 3,268 patients (90.2%) were analysed.

The study population showed a male predominance (63.5%) with a mean age of 56.9 years. Dyslipidaemia had been diagnosed for an average of 12.0 months (± 9.2) before the visit, usually by the survey's doctor (91.5%). At the time of diagnosis of dyslipidaemia, patients had a mean BMI of 27.6 kg/m², 45.4% of the patients were overweight ($25 \text{ kg/m}^2 \leq \text{BMI} < 30 \text{ kg/m}^2$), and 26.4% were obese ($\text{BMI} \geq 30 \text{ kg/m}^2$). The mean waist circumference at the time of diagnosis was 99.3 cm, 56.8% of the patients had a markedly increased waist circumference ($\geq 88 \text{ cm}$ for women and $\geq 102 \text{ cm}$ for men). Few patients (12.1%) had no cardiovascular risk factors, 72.6% of the patients had at least 1 risk factor and 15.3% had a history of cardiovascular disease. The most frequent modifiable cardiovascular risk factors were hypertension (49.9%), current smoking or smoking cessation within the previous 3 years (43.1%) and family history of early coronary disease (24.7%). The cardiovascular protective factor "HDL- cholesterol greater than or equal to 0.60 g/l (1.5 mmol/L)" was present in 23.0% of the patients at the time of diagnosis.

In terms of previous cardiovascular events, 6.1% of the patients had a history of coronary artery disease (with or without a revascularization procedure), 4.4% had a history of

occlusive peripheral arterial disease, 3.2% had a history of stroke or transient ischaemic attack and 2.2% had a history of myocardial infarction.

Overall, a lipid assessment was available at the time of diagnosis of dyslipidaemia for 94.1% of the patients. On average, this assessment was performed on the day of diagnosis at the survey doctor's request for 92.0% of the patients. For 98.6% of the patients, dietary and lifestyle advice was provided at the time of management of dyslipidaemia. These measures were generally implemented at the time of diagnosis, and consisted of orally presented dietary advices for 88.6% of the patients. The first dietary and lifestyle measures were initiated by the survey's doctor in 92.2% of the cases.

The median interval between diagnosis of dyslipidaemia and introduction of the first cholesterol-lowering drug therapy was 2.9 months; cholesterol-lowering drug therapy was initiated more than 3 months after the diagnosis for 43.0% of the patients, within the 3 months following the diagnosis for 23.9% of the patients, and within the 3 months preceding the diagnosis for 33.1% of the patients. For a great majority of patients (91.9%), the prescribed treatment was a statin and the prescription was made by the survey's doctor for 92.2% of the patients.

Patients follow-up was set up in 99.9% of the cases, with at least one annual lipid assessment for 91.4% of the patients.

Responses to the primary objective (analysed patients population)

The primary objective consisted of describing the time to initiation of cholesterol-lowering drug therapy in the management of dyslipidaemic patients according to various cardiovascular risk factors groups.

As described above, cholesterol-lowering drug therapy was initiated more than 3 months after the diagnosis for 43.0% of the patients, within the 3 months following the diagnosis for 23.9% of the patients, and within the 3 months preceding the diagnosis for 33.1% of the patients.

The time to initiation of cholesterol-lowering drug therapy varied only slightly according to the number of risk factors, but rather as a function of the type of prevention (primary or secondary): patients in secondary prevention (e.g. personal history of coronary artery disease, etc.) were more frequently treated within the 3 months preceding the diagnosis of dyslipidaemia than patients in primary prevention ($p < 0.001$). These results were confirmed by those derived from the logistic regression model: patients in secondary prevention had a 2.2-fold greater chance of being treated with a cholesterol-lowering drug during a period of [-3; 3] months in relation to the diagnosis of dyslipidaemia, than patients in primary prevention.