

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: NA

ACTIVE INGREDIENT: NA

Study No:

NIS-CIN-DUM-2010/1

A non-interventional, cross sectional, epidemiological study on the management of dyslipidemia in adult Type 2 diabetes mellitus patients in India (SOLID).

Developmental Phase: Phase 4

Study Completion Date: August 2012

Date of Report: 25th Feb 2013

OBJECTIVES:

Primary objective

To establish the proportion of patients reaching Low density lipoprotein (LDL-C) goals as per American diabetic Association (ADA) 2010 guidelines by assessing fasting blood lipids in the Indian diabetic population treated with lipid lowering drugs (LLDs).

Secondary objectives

- To establish the proportion of patients reaching LDL-C goals as per ADA 2010 guidelines by assessing fasting blood lipids in the Indian diabetic population treated with lipid lowering drugs (LLDs) as per age and gender.
- To assess the control of dyslipidemia based on one or more parameters of dyslipidemia (LDL-C, HDL-C or TG) by Statins alone or in combination with other LLDs as per ADA 2010 guidelines.
- To assess the control rates of dyslipidemia in 4 zones (North, South, East, West) of India.
- To record the commercially available brands of LLDs used in the treatment.

METHODS:

This was a multi centre, non-interventional, cross sectional, epidemiological study. Diabetic patients on lipid-lowering pharmacological treatment, who had given written consent and at a stable dose for at least 3 months prior to enrolment, were studied

RESULTS:

The study was carried out on 5400 patients (56.42% males, 43.58% females). Mean age, height, weight and BMI of patients were 54.03 years, 162.18 cm, 70.24 kg, and 26.81 kg/m² respectively. Mean systolic and diastolic blood pressure was 133.05 and 83.38 mm of Hg respectively.

- Over all mean LDL, HDL, Total Cholesterol and Triglycerides levels for these patients were 102.88 mg/dL, 43.91 mg/dL, 171.70 mg/dL and 153.39 mg/dL respectively.
- Among those with Overt CVD (n=306), only 22.87% (n=70) achieved the target LDL-C level of < 70 mg/dl and those without Overt CVD (n=5094), only 50.29% (n=2562) achieved the target LDL-C levels <100 mg/dl.
- Among the patients with Overt CVD, target LDL <70mg/dl was achieved by female patients in 13.76% (15 out of 109) and by male patients in 27.92% (55 out of 197), whereas among the patients without Overt CVD, target LDL <100mg/dl was achieved by 48.61% (1082 out of 2226) and 51.60% (1480 out of 2868); by female and male patients respectively.
- Control of LDL-C level by Age as per ADA goals

Target LDL-C Levels	Age, Percentage (n)		
	<40	≥40 &<55	>55
<70 mg/dl *	0.65(2)	4.25(13)	17.97(55)
<100 mg/dl #	5.24(267)	18.17(953)	26.34(1342)

- Control of Dyslipidemia across various zones

	Target Levels	North Percentage (n)	East Percentage (n)	West Percentage (n)	South Percentage (n)
LDL	<70 * & 100# mg/dl	47.19 (512)	54.48 (213)	53.94 (925)	44.45 (982)
HDL	<40 & 50 mg/dl	41.20 (447)	48.85 (191)	41.40 (710)	35.58 (786)
TG	<150 mg/dl	58.89 (639)	63.94 (250)	59.94 (1028)	53.87 (1190)
TC	< 240 mg/dl	93.92 (1019)	95.14 (372)	95.22 (1633)	88.59 (1957)

* With Overt CVD, # without Overt CVD

- The most commonly prescribed brands in the study population were CRESTOR (AstraZeneca), Storvas(Ranbaxy), Ecosprin AV(USV), Atorva (Zydus Cadila) and Rosuvas (Ranbaxy).
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