AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Atacand

ACTIVE INGREDIENT: Candesartan

Study No: NIS-CKR-ATA-2007/2
CMBAT study (COmpliance and efficacy in Mono and comBination tablet study ATacand/Atac and plus)

Developmental phase: Marketed

Study Completion Date: 2008.10.01

Date of Report: 2009.7.10

OBJECTIVES :

This study is to address the compliance and satisfaction of hypertensive patients prescribed Atacand or Atacand Plus under the clinician's judgment in a clinical practice setting, and to identify the relationship with blood pressure control rate.

Primary Objective :

Analysis of the compliance and satisfaction of hypertensive patients taken Atacand or Atacand Plus for over 8 weeks or longer

Secondary Objective :

The blood pressure control rate (attainment rate to the treatment goal suggested in the JNC 7th g uideline) of hypertensive patients taken Atacand or Atacand Plus for 8 weeks or longer

METHODS:

This no-interventional study protocol was reviewed according to the standard procedures of AstraZeneca. This clinical trial is a domestic, multi-centre, prospective non-interventional study to address the compliance, satisfaction of patients with hypertension prescribed Atacand and Atacand Plus under the clinician's judgment in a clinical practice setting, and to identify the relationship with blood pressure control rate. This non-interventional study will be conducted in a clinical setting: patients were diagnosed of essential hypertension before the entry to the study, th e prescription of Atacand or Atacand Plus was already determined by primary health care provide r, and taking part in the study will not affect treatment which the patients receive. The procedures of this clinical study and assessments to be done at each visit will be presented in Study Flow Ch art. At each visit clinical parameters are measured at the clinician's discretion and, among them, the following information will be collected:

RESULTS:

Total 8,981 patients were enrolled in this study and data from these patients were used for analysis. The demographic information of the patients enrolled in the study was summarized as following (Table 1)

Table 1. Baseline characteristics

Category		No. of subjects N (%)
Gender	Male	4535 (50.5)
	Female	4446 (49.5)
Age	Mean ± SD (year)	60.19 ± 12.26
	Min-Max	9 ~ 101
Patient type	In Patient	121 (1.35)
	Out Patient	8860 (98.65)
Duration*	Mean ± SD (year)	4.56 ± 5.65
	Min-Max	0 ~ 70.68
Present therapy	Life Style Modification	426 (4.74)
	Medication	8179 (91.07)
	Not applicable	376 (4.19)
Risk Factor[1)]	Diabetes Mellitus	1522 (16.95)
	Chronic Kidney Disease	377 (4.20)
	Smoking	1272 (14.16)
	Coronary disease	1180 (13.14)
	Dyslipidemia	1447 (16.11)
	Premature coronary artery disease	195 (2.17)
	Family history	1702 (18.95)
	Age	2896 (32.25)
	Not applicable	2680 (29.84)

*Missing : 3740 (person) , 1) Overlap

In survey of compliance and satisfaction, total 8,924 patients (99.37%) were reported that medication was not discontinued. Regarding on the reason for discontinuation, patient's request was 22 patients (38.60%) followed by adverse event 6 patients (10.53%).

As a result of analysis of patient satisfaction, 8,830 patients (98.32%) were surveyed being satisfied with treatment. In classification of reason for satisfaction with overlap count, blood pressure decrease was 7,116 patients (80.59%) followed by convenience for taking medication (n=2,270, 25.71%) and side effect (n=1,509, 17.09%). In dissatisfaction, blood pressure decrease was 133 patients and side effect was 9 patients.

In compliance, total 8,905 patients (99.15%) were compliant with treatment. Regarding on reason for non compliance, 44 patients (57.89%) were not complied due to lack of understanding their disease. Other reasons were lack of reliability for treatment (n=15, 19.74%) and increase in concomitant medication due to concurrent disease (n=13, 17.11%) and so on (Table 2).

Table 2. Compliance & Satisfaction

		No. of subjects N (%)
Medication continuance	Continuation	8924 (99.37)
	Discontinuation	57 (0.63)
	Adverse event	6 (10.53)
	Lack of Efficacy	0 (0.00)
	Patient's request	22 (38.60)
	Others	29 (50.88)
Patient satisfaction	Satisfaction	8830 (98.32)
	Blood pressure decrease	7116 (80.59)
	Side effect	1509 (17.09)
	Convenience for taking medication	2270 (25.71)
	Cost economic	406 (4.60)
	Dissatisfaction	151 (1.68)
	Blood pressure decrease	133 (88.08)
	Side effect	9 (5.96)
	Convenience for taking medication	0 (0.00)
	Cost economic	10 (6.62)
Patient compliance	Compliant	8905 (99.15)
	Non compliant	76 (0.85)
	Lack of reliability for treatment	15 (19.74)
	Side effect	3 (3.95)
	Increase in concomitant medication due to concurrent disease	13 (17.11)
	Lack of understanding of disease	44 (57.89)
	Others	4 (5.26)

Overlap count for all subitem

In analysis of blood pressure reduction effect, comparing blood pressure between before and after treatment, systolic blood pressure decreased from 148.79±13.96 mmHg to 129.92±11.20 m mHg and the diastolic blood pressure decreased from 91.71±10.97 to 81.64±9.33 with syntactical significance (p<.0001).

Table 3. Change of blood pressure

	Before	After	Difference	p-value†
	Mean ±SD(mmHg)	Mean ±SD(mmHg)	Mean ±SD(mmHg)	
SBP 8,979	148.79±13.96	129.92±11.20	18.87±12.82	<.0001
DBP 8,975	91.71±10.97	81.64±9.33	10.07±8.67	<.0001

†paired t-test

Missing (person): SBP (2), DBP (6)

In adverse event, adverse events occurred in 21 patients (0.23%) and the most frequently occurred adverse event was dizziness (n=13, 0.14%).