

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A

ACTIVE INGREDIENT: N/A

Study No: NIS-CKR-DUM-2008/4

Retrospective treatment pattern survey for the patient with and without history of stroke (SAPIENCE)
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Developmental phase: Marketed

Study Completion Date: 2009-5-31

Date of Report: 2009-11-25

OBJECTIVES:

Primary objective

- To compare treatment pattern of stroke patients with non-stroke patients receiving medical care from outpatient clinics at Neurology centers

* Target blood pressure will be analyzed with two criteria for the control of blood pressure; 140/90mmHg, the criteria in National Health and Nutrition Examination Survey conducted by the Ministry of Health and Welfare; and 130/80 mmHg recommended in 2007 ESH-ESC guideline for the management of arterial hypertension.⁸⁾

Secondary objective

- To evaluate target BP achievement rate in patients with stroke compared to patients without stroke.
- To investigate factors affecting BP target goal efficacy in patients with or without stroke.

METHODS:

This non-interventional observation study protocol was reviewed in accordance with the standard procedures of AstraZeneca. This clinical study will collect basic clinical data on

patients in order to assess attainment rate to target BP and to find factors associated with BP achievement in hypertension patients receiving medical care at neurology tertiary care centers, either with or without stroke history.

This study will keep a record of the following data on patients selected through medical record review. (Record in e-CRFs.)

Patient Enrollment: Patients, who coming to the Neurology Department during Jan, 2008 ~ Feb. 2008, will be consecutively enrolled.

In compliance with inclusion/exclusion criteria, patients will be enrolled in consecutive order and the investigator may enroll up to 50 patients.

RESULTS:

Subject's information

A total of 1,020 subjects at 12 centers participated in this study. The proportion of male subjects was relatively higher. The mean age and weight of the subjects were 65.8 years and 64.2 kg, respectively. In the group of 567 subjects with a past history of stroke, the mean time elapsed since stroke and age at onset of stroke were 2.4 years and 63.6 years, respectively (Table S1).

Table S1. Summary of Subject's demographics

Items			
Sex (N=1020)	Male	n(%)	554(54.3%)
	Female	n(%)	466(45.7%)
Age (years) (N=1020)		Mean±SD	65.8±11.0
Weight (kg) (N=1641)		Mean±SD	64.2±10.7
Time elapsed since stroke (years), N=567		Mean±SD	2.4±5.7
Age at onset of stroke (years), N=567		Mean±SD	63.6±13.7

Classification of stroke

Of 567 subjects with the stroke history, 58 (10.2%) had TIA; 489 (86.2%), ischemic stroke; and 20 (3.5%), hemorrhagic stroke 20 (3.5%).

Table S2 Summary of stroke history

Subjects with stroke history	567
Classification of stroke	n(%)
TIA (Transients Ischemic Attack)	58(10.2)
Ischemic Stroke	489(86.2)
Hemorrhagic Stroke	20(3.5)

Administration information of anti-hypertensive agents

The antihypertensive agents were given to approximately 89~93% of the subjects. Among them, ARBs were administered the most. During the follow-up period, 621 did not change the antihypertensive agents and 345 changed them (including addition and exclusion of the agents) (Table S 3).

The pattern of the antihypertensive agent administration was examined according to whether a subject had the stroke history or not. As a result, the proportion of the antihypertensive agent use was higher in the group of the subjects with the stroke history at both initial and final visits. The proportions of the antihypertensive agent use in the group of the subjects with the stroke history were not different at the initial and final visits, whereas the proportion in the group of the subjects without the stroke history increased by about 6% at the final visit compared to the initial visit (Table S4).

Table S3. Summary of administration information of anti-hypertensive agents (N=1020)

	At initial visit n(%)	At final visit n(%)
Subjects taking anti-hypertensive agents	912(89.4)	947(92.8)
Anti-hypertensive agents		
Diuretics	76(7.5)	86(8.4)
ARB	547(53.6)	629(61.7)
β-Blockers	118(11.6)	136(13.3)
Ca ²⁺ Channel Blockers	388(38.0)	398(39.0)

	At initial visit n(%)	At final visit n(%)
ACE Inhibitor	51(5.0)	33(3.2)
ARB/diuretic combination	92(9.0)	152(14.9)
Other combination	3(0.3)	4(0.4)

Table S4. Summary of anti-hypertensive agents administration according to whether a patient has stroke history or not

	Stroke history (Yes) N=567	Stroke history (No) N=453
At initial visit	534(94.2%)	378(83.4%)
At final visit	543(95.8%)	404(89.2%)

Efficacy evaluation

Whether 563 subjects who set the target blood pressure (BP) achieved the target BP (140/90 mmHg, 130/80 mmHg, or 120/80 mmHg) was evaluated at the initial and final visits according to whether a subject had the stroke history. As a result, the achievement rate of target BP in 400 subjects with the stroke history was 18.5% at the initial visit and increased by about 50% to 67.3% at the final visit. The achievement rate in 163 subjects without the stroke history increased by about 64% (Table S5).

Table S5. Achievement rate of target BP differently set according to whether a patient has stroke history or not

	Stroke history (Yes) N=400	Stroke history (No) N=163	p-value
At initial visit	74(18.5%)	11(6.8%)	0.0004
At final visit	269(67.3%)	115(70.6%)	0.3648

In addition, the proportion of the subjects who achieved the target BP (130/80mmHg) among all the subjects including those who did not set the target BP was evaluated according to whether a subject had the stroke history and by visit.

When the target BP was 130/80 mmHg, the achievement rate of target BP increased by

42% in the group of the subjects with the stroke history and 42% in the group of the subjects without the stroke history. The analysis of change of blood pressure according to whether a subject had the stroke history showed SBP and DBP in the group of the subjects without the stroke history decreased 1.0 mmHg and 1.5 mmHg more, respectively, than the group of the subjects with the stroke history (Table S6).

Table S6. Change of blood pressure and achievement rate of target BP

Stroke history	Item	At initial visit	At final visit	Change	Achievement rate of target BP (At initial visit)	Achievement rate of target BP (At final visit)
Yes	SBP (N=567)	145.2±16.7	128.4±11.0	-16.8±17.4	95(16.8%)	335(59.1%)
	DBP (N=567)	84.7±12.3	74.8±8.8	-10.0±12.5		
No	SBP (N=453)	146.6±14.4	128.8±11.2	-17.8±13.8	57(12.6%)	247(54.5%)
	DBP (N=453)	90.5±12.9	79.0±11.2	-11.5±11.0		

The antihypertensive effect of each administered antihypertensive agent was compared. As a result, the subjects treated with the combination of ARBs/diuretics showed the largest increase in the achievement rate of the target BP and the best antihypertensive effect.