AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No applicable
ACTIVE INGREDIENT: No applicable

Study No: NIS-CFR-DUM-2008/1
SERENITE **:** Observational survey on the clinical characteristics of hypertensive patients 75 years and older followed in general practice, according to their renal damage.

Developmental phase: No applicable
Study Completion Date: LSLV = 01 July 2009
Date of Report: 07 June 2010

OBJECTIVES:

The primary objective of the SERENITE survey was to describe the clinical characteristics of hypertensive patients 75 years and older followed in general practice, according to their renal damage.

METHODS and RESULTS :

A total of 4,474 patients were included by 1,493 general practitioners and data for 4,409 patients (98.5%) of the eligible population were analysed. The mean age of this population was 80 years (± 4.1 years) with 52.0% of females. The majority of patients were overweight or obese (65.5%). More than half of the patients (59.2%) had hypertension diagnosed for more than 10 years and the majority of the patients (72.2%) were followed by a cardiologist. Close to one half of patients (49.0%) had a history of at least one cardiovascular disease, mainly coronary heart disease (20.4%) and/or heart failure (18.7%). Two-thirds of patients (65.5%) had at least one risk factor, predominantly dyslipidaemia (55.3%) and/or diabetes (22.7%). Comorbidity was present in 41.5% of patients: depression (17.6%), cognitive disorders (13.8%) and chronic renal failure (13.1%). Blood pressure measurements in the supine/sitting position showed a mean SBP of 143.6 mmHg (± 14.7) and a mean DBP of 82.4 mmHg (± 9.6). Mean serum creatinine was 95.7 µmol/L (± 29.4). Mean creatinine clearance, calculated from serum creatinine according to the MDRD formula, was 66.0 mL/min (± 20.6).

Renal damage was defined by creatinine clearance < 60 mL/min. A total of 37.3% of patients had renal damage. Only 29.2% of patients with creatinine clearance serum < 60 mL/min were diagnosed with chronic renal failure and, inversely, 3.6% of patients considered to have chronic renal failure had a creatinine clearance > 60 mL/min.

Patients with renal damage presented the following clinical characteristics more frequently than patients without renal damage:

- 80 years and older (50.6% vs 41.5%)
- female gender (65.1% vs 44.1%)
- hypertension diagnosed at least 10 years ago (65.7% vs 55.4%),
- history of at least one cardiovascular disease (58.6% vs 43.3%)
- at least one risk factor (73.2% vs 60.9%)
- 2 or more risk factors (31.6% vs 17.3%),
- at least one comorbidity (47.0% vs 38.2%).

In contrast, weight, height, body mass index and blood pressure measurements and the blood pressure goals defined by the general practitioner were similar between patients with and without renal damage. Blood pressure goals were SBP/DBP ≤ 150/90 mmHg for 97.8% of patients, SBP/DBP ≤ 140/90 mmHg for 90.6% of patients and SBP/DBP ≤ 130/80 mmHg for 35.8% of patients.

A number of secondary objectives were also evaluated in this survey.

The proportion of patients with renal damage increased with age: 33.4% between the ages of 75 and 79, 40.8% between the ages of 80 and 84, 44.2% between the ages of 85 and 89 and finally 48.1% in patients 90 years and older. Patients younger than 80 presented renal damage significantly less often than patients 80 years and older.

Analysis of global drug management showed that 99.3% patients were taking *antihypertensive treatments*, a majority of patients (77.4%) were taking 1 to 6 *cardiovascular treatments*, mostly including statins and platelet aggregation inhibitors (63.1% and 52.2%, respectively), 38.6% of patients were taking 1 to 4 *psychotropic treatments* (63.4% were taking benzodiazepines/hypnotics, 31.8% were taking antidepressants and 22.8% were taking treatments for memory disorders) and 45.4% of patients were taking other treatments, mainly analgesics (66.1%).

Specifically concerning antihypertensive treatment, the majority of patients were taking monotherapy or dual therapy (73.8%), 36.4% of patients were taking monotherapy, 37.4% were taking dual therapy, 26.2% were taking three or more drugs. Patients with renal damage were less frequently treated with monotherapy (28.7%) than patients without renal damage (40.9%); patients with renal damage were more often treated with two or more than two drugs (38.9% and 32.4%, respectively) than patients without renal damage (36.4% and 22.6%). One half of patients were taking an angiotensin II receptor antagonist (ARAII) (54.7%) and diuretics (48.8%), followed by calcium channel blockers (34.1%), beta-blockers (27.0%) and angiotensin-converting enzyme (ACE) inhibitors (24.4%). The prescription of antihypertensive treatments was modified at the end of the visit for 31.2% of patients of the study. Treatment modification most frequently consisted of replacing one antihypertensive drug by another (39.8%), adding an antihypertensive drug (32.2%) or increasing the dose of antihypertensive drug (29.0%). The dose of antihypertensive drug was almost never decreased (0.4%) or stopped (1.5%).

Factors influencing antihypertensive management strategies were identified. Decisive factors at the limit of 20% in univariate analysis were entered into the logistic regression model.

The probability of being treated with *ACE inhibitor and/or ARAII monotherapy or combination therapy* was higher in males (Odds Ratio (OR) = 1.3), in patients with a diagnosis of HT for 10 to 20 years (OR = 1.4), patients followed by a cardiologist (OR = 1.4) and patients with SBP/DBP values less than 160/100 mmHg (OR between 2 and 2.8) (Hosmer and Lemeshow test significant at the limit of 5% indicating unsatisfactory adjustment). The probability of being treated with ACE inhibitor and/or ARAII was higher (OR about 1.2) in patients with renal damage than in patients without renal damage.

Factors increasing the probability of being treated with *monotherapy (vs dual therapy*) were a diagnosis of hypertension for less than 5 years vs 20 years or longer (OR = 2.6), and SBP/DBP in supine/sitting position ≥ 160/100 mmHg vs < 130/80 mmHg (OR = 2).

The probability of being treated with *monotherapy/dual therapy (vs triple therapy or more than three drugs*) was higher in patients with a diagnosis of hypertension for less than 5 years and for 5 to 10 years (OR = 4.1 and 2.2, respectively) and in patients with no risk factors (OR = 2.2) and lower in patients with a cardiovascular history (OR between 0.6 and 0.7).

Finally, the probability of being treated with *ACE inhibitor or ARAII + diuretics +/- beta-blocker vs ACE inhibitor or ARAII + calcium channel blockers +/- Beta-blocker* increased with the presence of heart failure (OR = 2.5) and a diagnosis of hypertension < 5 years (vs 20 years and longer).