AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not applicable
ACTIVE INGREDIENT: Not applicable

Study No: NIS-CFR-DUM-2009/1
Evaluation of target organs damage in hypertensive patients with no known cardiovascular (CV) or kidney disease, stratified according to blood pressure control.

Developmental Phase: Not applicable
Study Completion Date: 01/12/2009
Date of Report: 4/11/2010

OBJECTIVES:

The primary objective was to evaluate the frequency of evaluation of target organs subclinical damage on patients with no known cardiovascular (CV) or kidney disease, taking into consideration the blood pressure level (controlled HBP or not).

METHODS:

The PreVENT-A survey was a multicentre, cross-sectional observational study assessing the frequency of evaluation of subclinical target organ damage in hypertensive patients with no known cardiovascular (CV) or kidney disease. This evaluation was stratified according to blood pressure (controlled hypertension (HT) - uncontrolled HT).

RESULTS:

The PreVENT-A survey was conducted from June to November 2009: 516 cardiologists included 1,029 patients and 952 patients were analysed.

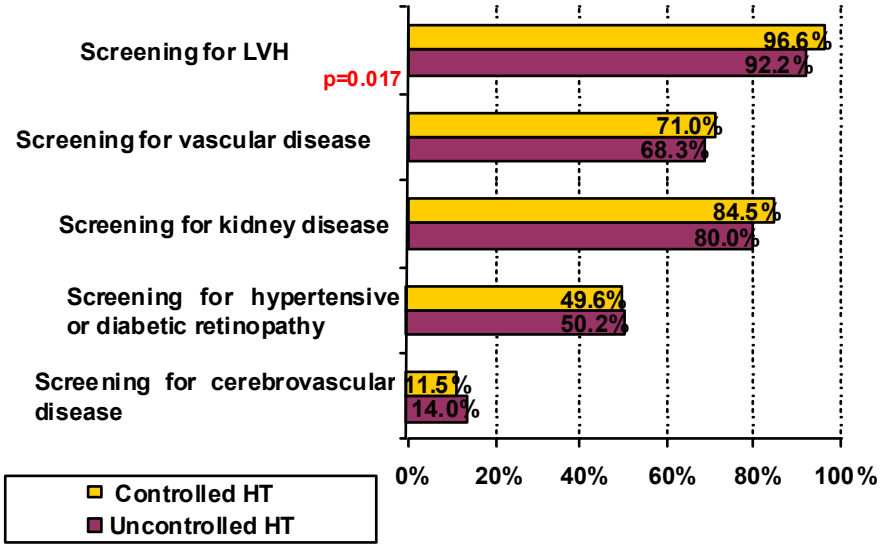
Of the **952 patients analysed**, 58.7% were males with a mean age of 61.6 ± 11.6 years. More than one third of these patients were retired (38.1%). On the day of the visit, mean blood pressure (MBP = SBP/DBP) was 145 ± 16 mmHg/85 ± 10 mmHg and HT had been diagnosed for an average of 7.7 ± 7.4 years. Patients had a mean BMI of 27.8 ±

4.6 kg/m^2, 43.0% were overweight and 27.7% were obese (WHO definition). 83.7% of patients were non-smokers or had stopped smoking for more than 3 years. One half of patients (49.2%) had a history of dyslipidaemia and 87.0% were taking treatment for dyslipidaemia; 17.5% of patients had diabetes, essentially type 2 (96.9%), which had been diagnosed for an average of 8.2 ± 7.3 years. A lipid and glucose test was available in 83.4% of patients and had been performed on average 3.8 ± 6.2 months previously. Fasting plasma glucose, total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides were available for one half of patients, and Hb_{A1c} was available for only one quarter of patients. An oral glucose tolerance test was rarely documented (0.6% of patients). One quarter of patients (26.1%) presented a metabolic syndrome and 13.6% had a family history of stroke. Less than 10% of patients presented an associated comorbidity (COPD, sleep apnoea syndrome, atrial fibrillation, cognitive disorders, erectile dysfunction). Cardiologists evaluated the global CV risk level of their patients as high or very high in 22.4% of cases.

Description of the population according to blood pressure control showed that more than two-thirds of patients (70.9%) had uncontrolled hypertension (systolic blood pressure greater than 140 mmHg and diastolic blood pressure greater than 90 mmHg for nondiabetic patients; or systolic blood pressure greater than 130 mmHg and diastolic blood pressure greater than 80 mmHg for diabetic patients).
No socio-demographic differences (age, gender, socioeconomic group) were observed between patients with controlled HT versus patients with uncontrolled HT. Patients with controlled HT had a mean BP of 129 ± 7/78 ± 6 mm Hg and patients with uncontrolled HT had a mean BP of 153 ± 14/88 ± 9 mm Hg. In patients with controlled HT, HT had been diagnosed for slightly longer than patients with uncontrolled HT (8.1 ± 6.9 years versus 7.5 ± 7.7 years), self-measurement of blood pressure was performed more frequently (39.8% versus 36.7%) and ABPM was performed more frequently (39.8% versus 33.2%). 1.9% of patients with controlled HT were diabetic versus 19.6% of patients with uncontrolled HT. The cardiologist estimated the patient's global CV risk level to be high or very high in 10.9% of patients with controlled HT and 26.3% of patients with uncontrolled HT.

At least one **screening procedure for subclinical target organ damage** had been performed for the very great majority of patients: 98.9% in patients with controlled HT and 96.9% in patients with uncontrolled HT. A mean of 3.1 ± 1.1 screening procedures were performed in patients with controlled HT versus 3.0 ± 1.2 in patients with uncontrolled HT. Only screening for left ventricular hypertrophy (LVH) was significantly different between the two patient groups: a screening procedure was performed in 96.6% of patients with controlled HT versus 92.2% of patients with uncontrolled HT ($p = 0.017$; Figure 1).

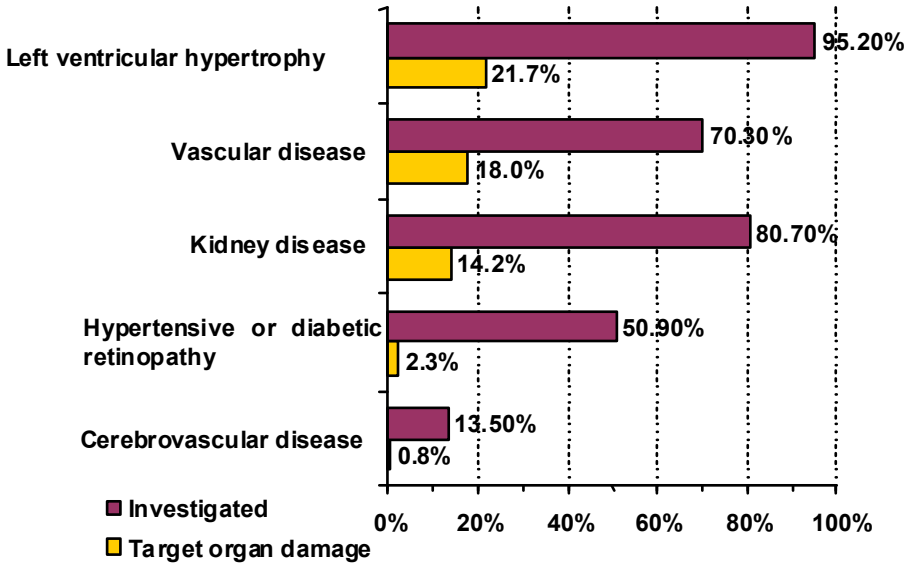
Figure 1: Screening for subclinical target organ damage



According to ESH 2007 guidelines, the diagnosis and management of HT depend on the **global CV risk level**, which takes into account CV risk factors, subclinical target organ damage and associated comorbidities, depending on BP values. The mean number of CV risk factors in the PreVENT-A survey was 1.9 ± 1.2. More than one third of patients (38.4%) presented at least one target organ damage (ESH 2007 criteria). The CV risk was high or very high for 30.6% of patients.

In the PreVENT-A survey, **subclinical target organ damage** (TOD) was defined according to ESH 2007 criteria with the addition of the following elements: an increased diameter of the abdominal aorta meaning the presence of subclinical vascular disease, positive proteinuria on urine dipsticks or proteinuria greater than 0.03 g/l meaning the presence of subclinical kidney disease, a diagnosis of retinopathy meaning the presence of hypertensive or diabetic retinopathy and lacunar lesions or microbleeding or an MMS score less than 24 meaning the presence of subclinical cerebrovascular disease. According to all of these criteria, 41.7% of patients presented subclinical damage of at least one target organ. Only one organ was affected in almost three-quarters (71.3%) of patients with TOD. The mean number of TOD per patient was 0.6 ± 0.8. LVH, vascular disease and kidney disease were the most frequently detected TOD (one in five or six patients) but also the most frequently investigated TOD (Figure 2).

Figure 2: Frequency of screening for target organ damage and frequency of at least one target organ damage (N = 952)



At the time of the visit, 88.8% of patients were treated for their HT: 44.6% of patients were taking ARBs, 43.3% of patients were taking at least one diuretic (thiazide, loop or potassium-sparing diuretics), 31.0% of patients were taking calcium channel blockers, 29.0% were taking beta-blockers, 18.8% were taking ACE Inhibitors and less than 10.0% were taking other antihypertensive drugs. These percentages were higher in the presence of TOD: ARBs (52%), diuretics (thiazide, loop or potassium-sparing diuretics) (56%), calcium channel blockers (39%), beta-blockers (35%), ACE inhibitors (22%) and other antihypertensive drugs (10%). The choice of treatment was not influenced by the type of TOD. Treatment remained unchanged after the visit in more than one half of cases.