AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not applicable
ACTIVE INGREDIENT: Not applicable

Study No: NIS-CFR-DUM-2009/2
Evaluation of target organs damage in hypertensive patients followed in general practice with no known cardiovascular (CV) or renal disease, stratified according to blood pressure control

Developmental Phase: Post-Marketing
Study Completion Date: 29/06/2010
Date of Report: 26 /04/2011

OBJECTIVES:

The primary objective was to evaluate the frequency of evaluation of preclinical target organs damage in hypertensive patients with no known cardiovascular or renal disease, by taking blood pressure (controlled or uncontrolled HT) into account.

METHODS:

The PreVENT-A GP study was a multicenter, observational, cross-sectional study to evaluate the frequency of investigation for subclinical damage of target organs in hypertensive patients without known cardiovascular (CV) or renal disease followed up by general practitioners. The study generated data additional to that of the PreVENT-A Cardio study conducted with cardiologists. The evaluation was stratified according to blood pressure control (controlled hypertension - non-controlled hypertension).

RESULTS:

The PreVENT-A GP study took place from January to June 2010: 943 general practitioners included 1881 patients, of whom 1778 were analyzed.

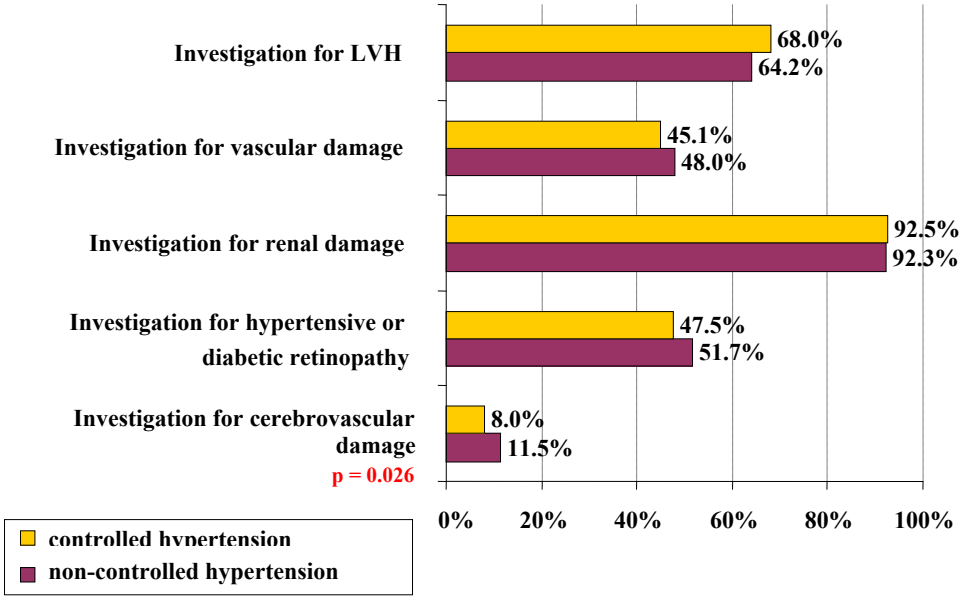
The **1778 patients analyzed** had a mean age of 60.7 ± 10.6 years and 64.1% were men. Over 40% of the patients had retired.
On the day of consultation, the mean blood pressure (BP = SBP / DBP) was 143 ± 14 mm Hg / 84 ± 9 mm Hg and the time since hypertension diagnosis was on average 7.7 ± 6.3 years. Self BP determination was used to confirm the diagnosis for 34.7% of the patients and to adjust treatment in 34.2% of the patients. In less than 1 patient out of 3 (29.4%), ambulatory blood pressure monitoring was conducted.

The patients had a mean body mass index (BMI) of 27.7 ± 4.9 kg/m^2; 45.3% were overweight and 25.7% obese (*WHO cutoffs*). In all, 79.4% of the patients were non-smokers or had quit smoking more than 3 years previously. Half of the patients (49.4%) presented with a history of dyslipidemia and 92.7% were on treatment for it. In all, 18.1% of the patients had diabetes, mainly of type 2 (91.1%). The time since diagnosis was on average 7.0 ± 6.2 years. Almost one third of the patients (31.3%) had a metabolic syndrome and 15.5% had a familial history of early cardiovascular (CV) events. Less than 10% of the patients presented with a concomitant disease (COPD, sleep apnea syndrome, complete arrhythmia due to atrial fibrillation, cognitive disorder, and erectile dysfunction). The general practitioners evaluated the overall CV risk for their patients as high or very high for 24.3% of the patients.

The population description according to blood pressure control showed that two thirds of the patients (66.8%) had non-controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure greater than 90 mm Hg for the non-diabetic patients; or, for the diabetic patients, systolic blood pressure greater than 130 mm Hg or diastolic blood pressure greater than 80 mm Hg).
Comparison of the patients with controlled hypertension and those with non-controlled hypertension did not show any socio-demographic differences (age, gender and socio-economic class). On the day of consultation, the patients with controlled hypertension had a mean blood pressure of 129 ± 6 / 77 ± 6 mm Hg; the patients with non-controlled hypertension had a mean blood pressure of 149 ± 13 / 87 ± 9 mm Hg.
The patients with controlled hypertension presented with less cardiovascular risk factors (1.8 vs. 2.3%, $p < 0.001$). Their BMI was lower (BMI ≥ 30 kg/m²: 16.6 vs. 30.2%) as was their waist circumference, particularly for men (≥ 102 cm (M): 34.6 vs. 60.6%). The patients with controlled hypertension were less frequently diabetic (3.8 vs. 25.5%), presented with metabolic syndrome less frequently (17.8 vs. 38.2%) and had a less frequent familial history of early cardiovascular events (11.2 vs. 17.6%).
Sleep apnea syndrome and erectile dysfunction were less frequent in patients with controlled hypertension (2.2 vs. 6.1% and 6.1 vs. 11.3%, respectively).
The physician's estimate of the overall CV risk level was high or very high for 13.6% of the patients with controlled hypertension and 29.8% of the patients with non-controlled hypertension.

At least **one investigation for subclinical damage of target organs had been conducted or was ongoing** for the vast majority of patients: 95.7% of the patients with controlled hypertension and 96.4% of the patients with non-controlled hypertension. On average, 2.6 ± 1.3 investigations were conducted irrespective of patient group. Only for investigation for cerebrovascular damage was there a significant difference between the groups of patients: investigation was conducted in 8.0% of the patients with controlled hypertension vs. 11.5% of the patients with non-controlled hypertension ($p = 0.026$; Figure 1).

Figure 1 – Investigation conducted or ongoing for subclinical damage of target organs

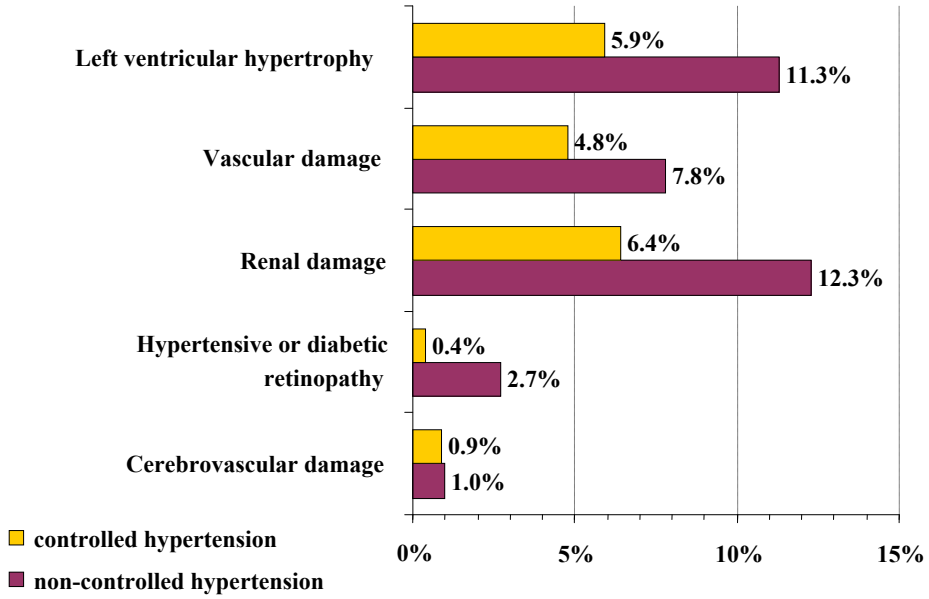


According to the ESH 2007 guidelines, the diagnosis and management of hypertension depends on the **overall CV risk level**, which takes into account blood pressure values, CV risk factors, subclinical damage of target organs and concomitant diseases. In the PreVENT-A GP study, the mean number of CV risk factors was 2.1 ± 1.3 with a significant difference between the 2 groups (1.8 for the patients with controlled hypertension vs. 2.3 for the patients with non-controlled hypertension, $p < 0.001$). In all, 13.2% of the patients presented with at least one target organ damage (8.7 vs. 15.4%, $p < 0.001$) (ESH 2007 criteria). The CV risk, calculated from the ESH 2007 guidelines, was strongly or very strongly exacerbated for 34.8% of the patients (19.9 vs. 42.3%, $p < 0.001$).

In the PreVENT-A GP study, the **subclinical damage of target organs** was defined on the basis of the ESH 2007 criteria together with the following: 1) if there was at least one pathological result in favor of vascular damage, the patient was considered to present with subclinical vascular damage; 2) if urinary dipstick proteinuria was positive or the proteinuria result was greater than 0.03 g/L or the glomerular filtration rate results were pathological, the patient was considered to present with subclinical renal damage; 3) if the investigation for retinopathy was positive, there was considered to be retinopathy; 4) if the results of the CT scan/MRI were in favor of cerebral damage or the MMS score was less than 24, there was considered to be subclinical cerebrovascular damage.
On the basis of all those criteria, out of the 1687 patients for whom at least one investigation was conducted, 21.9% presented subclinical target-organ damage, with a significant between-group difference (15.9 for the patients with controlled hypertension vs. 24.5% for the patients with non-controlled hypertension, $p < 0.001$). Only one organ was involved in 73.2% of the patients presenting with subclinical target-organ damage (86.2 vs. 68.5%, $p = 0.013$). The number of subclinical target-organ damages per patient was, on average, 0.3 ± 0.6 damages (0.2 vs. 0.4, $p < 0.001$). Renal damage, left ventricular hypertrophy and vascular damage were the most frequently identified

(between 7 and 10%), but also the damages for which investigation was most frequently conducted.

Figure 2 – Frequency of at least one subclinical target organ damage according to blood pressure control (controlled or non-controlled BP) in the patients with at least one damage (N = 357)



At the time of the consultation, over 93% of the patients were treated for hypertension : 54.9% of the patients were treated with an angiotensin II receptor blockers, 30.1% of the patients received at least one diuretic (thiazide, loop or potassium-sparing diuretic), 21.8% received a calcium channel blockers; 17.4% a β-blockers, 15.9% received an ACE inhibitors and 5.5% another antihypertensive. The choice of treatment was not influenced by the type of subclinical target organ damage. In more than half of the cases, the treatment remained unchanged after the consultation.