

STUDY REPORT SYNOPSIS

Finished product: not applicable

Active ingredient: not applicable

Study No. NIS-CRS-DUM-2010/2

An epidemiological study to evaluate standard daily practice in managing patients with arterial hypertension and to evaluate patients' quality of life

Developmental phase: IV (non-interventional study)

Study completion date: 06 Dec 2011

Date of Report: 30 July 2012

OBJECTIVES:

(a) Primary objective: The primary objective of this NIS was to evaluate proportion of patients on antihypertensive pharmacological treatment reaching SBP goals according to the ESC 2007 guidelines (<140 mmHg*).

(b) Main secondary objectives:

- Evaluate proportion of patients on antihypertensive pharmacological treatment reaching DBP goals according to the ESC 2007 guidelines (<90 mmHg*).
- To evaluate proportion of patients on antihypertensive pharmacological treatment reaching combined SBP and DBP treatment goals according to the ESC 2007 guidelines (SBP <140 mmHg and DBP <90 mmHg*).
- To evaluate patients quality of life after 12 and 24 weeks by using patients quality of life questionnaire.
- To evaluate patients' compliance after 12 and 24 weeks by using patients quality of life questionnaire.
- To collect local epidemiological data on patients with hypertension (demographic data; hypertension management data: treatment, treatment changes and tolerability data).

METHODS:

Patients had four study related-visits: visit 1 (baseline), visit 2 (6 weeks±2 weeks after visit 1) and visit 3 (12 weeks±2 weeks after visit 1) and last one after 24 weeks. 3 visits (the first one, second after 12 weeks and the third/last one after 24 weeks) were also acceptable if it was in line with everyday practice. The following tools were used: recording of data in CRF (by investigator) at each visit and patients' questionnaire (visit 1, visit 3 and 4).

RESULTS:

The study was conducted in 11 centres with the participation of 32 cardiologists. They included a total of 306 patients in the study. Among 306 patients that were included in this non interventional study, 122 of them (41.4%) had hypertension grade I, 131 patients (44.4%) had hypertension grade II, 42 patients (14.2%) had hypertension grade III.

(a) Primary objective:

- SBP treatment goal:
 - Overall, 57.1% out of all 306 patients enrolled in this non interventional study reached SBP treatment goals by visit 4, according to the ESC 2007 guidelines (<140 mmHg or <130 mmHg*).
 - In subgroup of patients with diabetes mellitus (DM), established CV disease and/or renal disease (n=145, 47.4%) the SBP treatment goal (<130 mmHg)* at visit 4 was achieved in 37.9% of patients.
 - In subgroup of patients (n=161, 52.6%) without diabetes mellitus, established CV disease and/or renal disease the SBP treatment goal (<140 mmHg)* at visit 4 was achieved in 73.2% of patients.

(b) Secondary objectives:

- DBP treatment goals:
 - Overall 52% out of all 306 patients with available hypertension data reached at visit 4 the DBP goals, according to the ESC 2007 guidelines (<90 mmHg or <80 mmHg*).
 - In subgroup of patients with diabetes mellitus (DM), established CV disease and/or renal disease (n=145, 47.4%) the DBP treatment goal (<80 mmHg) was achieved at visit 4 in 20.5% of patients.
 - In subgroup of patients (n=161, 52.6%) without diabetes mellitus, established CV disease and/or renal disease the DBP treatment goal (<90 mmHg) was achieved at visit 4 in 73.2% of patients.
- SBP and DBP treatment goals:
 - Overall, 44.6% (129) out of all 306 patients with available hypertension data reached at visit 4 the SBP and DBP treatment goals according to the ESC 2007 guidelines (<140/90 mmHg or <130/80 mmHg*).
 - In subgroup of patients with diabetes mellitus (DM), established CV disease and/or renal disease (n=145, 47.4%) the SDB and DBP treatment goal (<130/80 mmHg) at visit 4 was achieved in 13.6% of patients.
 - In subgroup of patients without diabetes mellitus (DM), established CV disease and/or renal disease (n=161, 52.6%) the SDB and DBP treatment goal (<140/90 mmHg) at visit 4 was achieved in 70.7% of patients.

*According to ESC 2007 guidelines, for patients with arterial hypertension who also have concomitant diabetes mellitus, renal disease and/or established cardiovascular disease (e.g. coronary disease), the target value for SBP is 130 mmHg, and/or 80 mmHg for DBP.

- Patients quality of life and compliance:

- Quality of life was assessed by using the patients' questionnaire. The symptoms questioned included: trouble with sleeping, problems performing daily activities, presence of exhaustion/weakness, presence of peripheral oedema, frequency of urination, presence of headache or ringing in the ear, chest pain at rest, presence of good mood. Patient compliance, i.e. adherence to treatment, was also self-assessed by patients by providing answers to several questions in the same patient's questionnaire.
- The results show that patients' quality of life and compliance/adherence improved in all parameters/symptoms questioned by visit 4, with statically significant improvement as compared to visit 1.
- Demographic data:
 - The study was conducted in 11 centres in Serbia with the participation of 32 cardiologists. They included a total of 306 patients in the study.
 - The average age of patients included in the study was 61 years with 53.3% being females.
 - 95 patients (32%) had coronary disease in personal history of illness, 32 patients (10.8%) had peripheral vascular disease, 12 patients (4.0%) had kidney disease, 30 patients (10.1%) had cerebrovascular disease, and 66 patients (22.2%) had diabetes.
 - Average body weight among female patients was 75 kg, and among male patients was 88 kg.
- Patients' management/treatment pattern:
 - The calcium antagonist monotherapy was given to 14.8% of patients, whilst 85.2% were on combination regimen.
 - The calcium antagonists used: felodipine (93.9% of patients), amlodipine (5.1%) and nifedipine (1%).
 - The antihypertensive drug used in combination with calcium antagonist was: ACE inhibitor (53.8%), beta blocker (23.1%) or diuretic (23.1%).
 - 186 patients (63.3%) were on 5 mg of calcium channel antagonists, and 66 patients (22.4%) used calcium channel antagonists in dose of 10 mg.
 - There was a decrease of the frequency of treatment change during the course of the study: treatment changed at visit 2, 3 and 4 in 27.9%, 16.2% and 10.6% patients primarily due to unregulated blood pressure. The most common treatment change was dosage increase of antihypertensive drug(s) in case of unregulated blood pressure.