AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Atacand
ACTIVE INGREDIENT: candersartancilexetil

Study No: NIS-CHR-ATA-2008/1

Developmental phase: Non-interventional study
Study Completion Date: 07/2010
Date of Report: 02/2011.

OBJECTIVES:

Primary Objective:

- To evaluate patient's clinical condition, in terms of symptom and clinical signs load, in patients with chronic heart failure treated with candesartan cilexetil for 24 (+/- 8) weeks

Secondary Objective:

- To evaluate left ventricular ejection fraction after 24 (+/- 8) weeks of treatment with candesartan cilexetil for
- To evaluate prescribing practices for candesartan cilexetil in the treatment of chronic heart failure in Croatia
- To evaluate compliance with the prescribed candesartan cilexetil treatment

METHODS:

Patient population

500 patients (outpatients or hospitalized patients) treated with candesartan cilexetil for chronic heart failure.

This study enrolled male and female patients aged 18 years and older with diagnosis of chronic heart failure who are already treated with candesartan cilexetil for 24 weeks (+/- 8 weeks)

Design

This study was non-interventional, prospective, cross-sectional, observational, epidemiological study Descriptive statistics will be used for evaluation of collected data.

This non-interventional study had one study visit.

Study was conducted by 50 cardiologist.

Each Investigator will recruit 5 to 15 patients with chronic heart failure meeting the study inclusion criteria. When patients visited HCP, the study details were explained to patient and he/she was asked to sign the Informed Consent in line with local regulations.
During the visit which has been at the time of 24 weeks (+/- 8 weeks) after the introduction of candesartan cilexetil for the treatment of chronic heart failure investigator filled in Case Report Forms (CRF). Data about candesartan cilexetil dose and clinical signs and symptoms at the time of introduction of candesartan cilexetil has been retrospectively entered into CRF

Table 1. Study plan

	Visit 1
Date of the visit	X
Date of signing ICF	X
Characteristics of the patients: • age • gender	X
Date of chronic heart failure diagnosis	
Data collected at the time of introduction of candersartan cilexetil (retrospective data):	
• Date of introduction of candesartan cilexetil and dose at the time of introduction	X
• Reason for introduction of candesartan cilexetil (adverse event, not satisfied with efficacy of previous treatment etc.)	X
• Was candesartan cilexetil introduced as monotherapy or in combination with other drug classes (generic names of drugs and doses)	X
• NYHA status at the time of candesartan cilexetil introduction	X
• Question on signs of fluid retention at the time of candesartan cilexetil introduction: o Presence of swollen ankles o Presence of hepatomegaly	X

○ Presence of ascites	
• Question on experiencing tiredness and fatigue at the time of candesartan cilexetil introduction	X
• Left ventricular ejection fraction (EF) value (if echocardiography was performed within 4 weeks before/after introduction of candesartan cilexetil)	X
Data on current candasartan cilexetil treatment (at Visit 1):	
• Candesartan cilexetil dose at the time of the visit	X
• Data on how many recommended candesartan cilexetil doses did patient take during last 7 days?	X
• Was candesartan cilexetil dose changed after introduction of candesartan cilexetil (date of changes and recommended doses)?	X
• Was other medication for CHF changed after introduction of candesartan cilexetil (description of changes)?	X
Symptoms and signs evaluation at the time of Visit 1:	
• NYHA status	X
• Question on signs of fluid retention at the time of candesartan cilexetil introduction:	X
○ Presence of swollen ankles	
○ Presence of hepatomegaly	
○ Presence of ascites	
• Question on experiencing tiredness and fatigue	X
• Left ventricular ejection fraction (EF) (if echocardiography was performed within 4 weeks before visit 1)	X
FURTHER RECOMMENDED TREATMENT	
• Recommended candesartan cilexetil dose at the end of the visit.	X
• If candesartan cilexetil will be discontinued, reason for discontinuation will be collected.	X
• AEs will be reported according to the requirements for spontaneous AE reporting in Croatia	X

Study Drug
Candesartan cilexetil

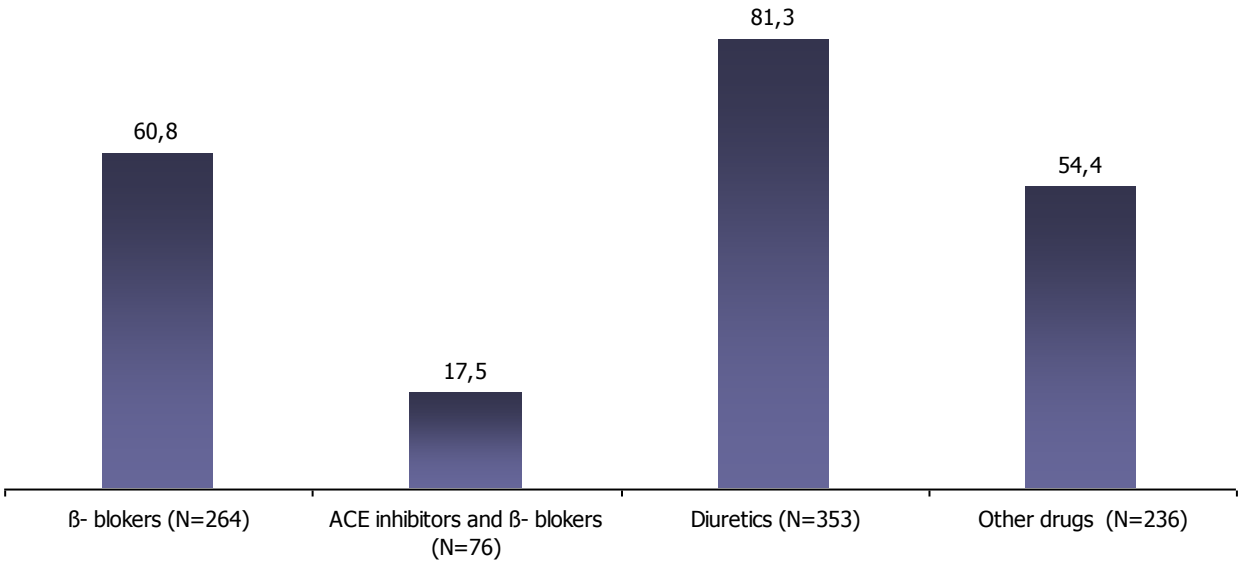
Statistical analysis
Descriptive statistical methods were used for data analysis.

RESULTS:

Demographics
In total, 435 patients were enrolled in the study of which 54,6% were male. Most patients were between 55 and 75 years old with minor proportions of patients younger than 35.

Data collected at the time of introduction of candesartan cilexetil (retrospective data)

Patients were required to be on candesartan cilexetil therapy for at least 24 weeks (+/- 8 weeks) prior to enrolment. In 34,6% of patients candesartan cilexetil has been introduced in treatment within one year after chronic heart failure diagnosed. In each tenth patient treatment with candesartan cilexetil has been start in same months when disease diagnosed.
At the moment of introduction candesartan cilexetil in treatment 50,5% of patients received candesartan cilexetil in a dose of 4 mg, 38,5% received dose of 8mg and 9,9% received dose of 16mg.
As a monotherapy candesartan cilexetil was prescribed in 1,8% of patients. The most frequent combined treatment were shown in Table 2.

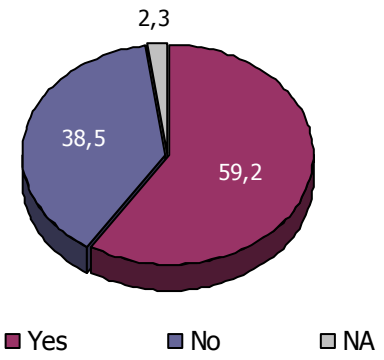


Reasons for introduction of candesartan cilexetil were: in 37,8% of patient physicians were not satisfied with efficacy of previous treatment ; in 31,8% of patient because of adverse event; in 6,9% of patients because of contraindications with concomitant therapy and in 14,3% of patients for other reason.

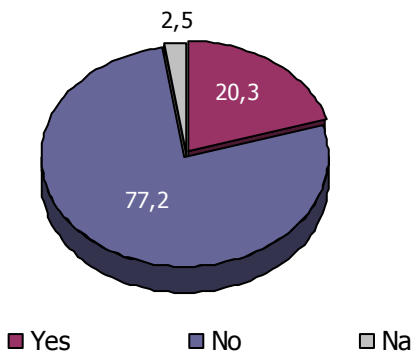
At the moment of introduction candesartan cilexetil signs of fluid retention were recorded within 1/3 of patients – presence of swollen ankles in 85% , presence of hepatomegaly in 25,2%, and ascites in 7,5% of cases.

Proportions of patients experiencing tiredness and fatigue at the moment of introduction candesartan cilexetil are shown in Graf 1 and proportions of patients experiencing tiredness and fatigue at Visit 1 are shown in Graf 2.

Graf 1.



Graf 2



Left ventricular ejection fraction (EF) value performed within 4 weeks before/after introduction of candesartan cilexetil have been available for 67,7% of patients. In 32,3% of patients heart ultrasound is not performed in that period. In the majority of patients (71,8%) EF value has been between 25 and 50%. EF value more than 50% were recorded in 14,6% of patients.

Left ventricular ejection fraction (EF) value performed within 4 weeks before Visit 1 have been available for 71,2% of patients. 63,2% of patients have had EF value between 25 and 50%. EF value more than 50% were recorded in 31,2% of patients.

Adverse event

No adverse events were reported in this study.